THE INTERNATIONAL CENTRE FOR THE SETTLEMENT OF INVESTMENT DISPUTES

In the Matter of Arbitration Between:	
APOTEX HOLDINGS INC. and APOTEX INC., Claimants,	Case No. ARB(AF)12/1
and	
THE UNITED STATES OF AMERICA, Respondent.	(Revised) Volume 4

HEARING ON JURISDICTION AND THE MERITS

Thursday, November 21, 2013

The World Bank
1225 Connecticut Avenue, N.W.
C Building
Conference Room C8-150
Washington, D.C. 20433

The hearing in the above-entitled matter came on, pursuant to notice, at 9:04 a.m. before:

MR. V.V. VEEDER, QC, President

MR. J. WILLIAM ROWLEY, QC, Arbitrator

MR. JOHN R. CROOK, Arbitrator

Also Present:

MR. MONTY TAYLOR
Secretary to the Tribunal

MS. MARTINA POLASEK
Alternate Secretary of the Tribunal

Court Reporter:

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C O N T E N T S

CONFIDENTIAL PORTIONS

P R O C E E D I N G S

PRESIDENT VEEDER: Good morning, ladies and gentlemen. We'll start Day 4 of this hearing, Thursday, the 21st of November.

Before we resume with the testimony, are there any housekeeping matters? Anything from the Claimant?

MR. LEGUM: Nothing from the Claimant.

PRESIDENT VEEDER: From the Respondent?

MR. DALEY: Yes, two small matters.

The first is yesterday there was some discussion--the Tribunal asked about a PowerPoint slide or set of PowerPoint slides relating to Teva, and you gave us a chance to consider whether to object to that. I just want to confirm we do not object to the admission of that document.

PRESIDENT VEEDER: We have that entered into the file and with an exhibit number.

MR. DALEY: What I'll do is I'll just read the Bates numbers for it. I thought that might suffice. But if you want to add an exhibit number, we could do that as well. So it begins at U.S. 000940

09:03:49 and concludes at U.S. 000990.

PRESIDENT VEEDER: Maybe the simplest thing is to give it the same exhibit number as the minutes of the meeting to which it was attached.

MR. LEGUM: That makes sense, with an "A" after the number?

PRESIDENT VEEDER: Exactly.

MR. LEGUM: So that would require us to simply remember what the number was for the minutes.

PRESIDENT VEEDER: I can't do that. That is above my pay grade, but you can do that.

MR. LEGUM: Yes, we'll come back to that.

PRESIDENT VEEDER: Okay. Just so there is no dispute about that. So we'll add that in. If you could have it electronically as well, once it's been marked up with the A number.

MR. LEGUM: Claimants will take care of that.

PRESIDENT VEEDER: Okay.

MR. DALEY: And the second matter is, as soon as our printer begins working again, we will hand out a chart which has the record citations from Mr. Bigge's presentation yesterday which were

09:04:39 references to the transcript of the day before. I had hoped to have it in my hand, but the printer is misbehaving, so I do apologize.

PRESIDENT VEEDER: No hurry about that. Thank you much for doing that.

In return, we have a very minor housekeeping matter; which is that we got this additional legal material from Mustafa Kamil Yasseen from the recueil des cours. If we could just have that electronically as well, that would be helpful. And also, just confirmation that, in fact, after this very interesting material, our passage really starts, for the purpose of this case, at Page 105.

MR. LEGUM: There is a specific section that addresses Article 33(4). I don't remember the page number on which it begins, but it is certainly correct that it is towards the end.

PRESIDENT VEEDER: Yeah. I think the first 104 pages are interesting but not directly relevant, and 33(4) starts with 105. If that's the wrong passage, please tell us.

MR. LEGUM: Very good.

09:05:39 CHAIRMAN: Nothing else? Let's have the Witness back.

PRESIDENT VEEDER: Good morning, sir. Welcome back. We resume your testimony, and I have to remind you that you are still operating under your Declaration as a Witness.

(No microphones.)

THE WITNESS: Okay.

PRESIDENT VEEDER: I think you have to say yes on the record.

THE WITNESS: Yes. Yes. Thank you.

CROSS-EXAMINATION (Continued)

BY MR. LEGUM:

Q. Good morning, Dr. Rosa.

A. Good morning.

Q. So we're going to continue the questions that we addressed yesterday, and I would, again, like to express our thanks to you for taking time away from your duties this morning to be with us.

A. Okay. You're welcome.

Q. I'd like to talk about Forms 483. The purpose of a Form 483 is to inform the pharmaceutical

867

firm of the inspector's observations; is that correct?
A. That's one of the purposes of that form, but the form in itself is not the only mechanism that an investigator has to convey concerns or inspectional observation. Just one of the forms, one of the ways.
Q. Now, the observations that are listed on a Form 483 do not reflect a final FDA determination concerning the firm's compliance; correct?
A. The observation on the 483 represent the observations made by the investigators during its time at the facility.
Q. So let me just make sure that I have an answer to my question.
A. Yeah.
Q. So the question is: The observations on the form do not reflect a final FDA determination concerning the pharmaceutical firm's compliance?
A. That's a correct assessment, yeah.
Q. Now, companies can respond to Forms 483; correct?
A. They can, yes.
Q. And FDA sometimes decides that a company's

868

response adequately addresses FDA's concerns; correct?
A. Yes.
Q. I'd like to direct you to Paragraph 20 of your First Witness Statement. And if you'd like, you can take a moment to read it again just to refresh your recollection.
A. Yes.
Q. So I'd like to direct your attention to the last sentence, which appears on Page 8. So you state there that it is your responsibility to review relevant information before deciding whether to take regulatory actions; correct?
A. Right, as the division director, I'm responsible for that--for the review that that office, that division makes. So that--my statement is, yes. It's my responsibility. Whatever happens there in terms of that review is my responsibility.
Q. Okay. So the answer to my question is yes?
A. Yes.
Q. Now, you describe this relevant information to include the firm's "promised and ongoing corrective actions"; correct?

869

A. That's what--if the question is do we review the information received in a response, that's one of the things that we do. We review the firm's response. But that's not the only factor, the only thing that we do when we're evaluating the case. There are many other factors and activities that go on when we're looking at a case.
Q. So, Dr. Rosa, I have a fair number of questions, and some of the questions, I think, will be difficult and you should feel free to explain any of your questions.
A. Right.
Q. But if it's possible to answer questions that can simply be answered with yes or no with a yes or no, we'll get through this much quicker.
A. I will try to do my best, but not everything can be answered with a yes or no. And I hope you understand that.
Q. Of course.
So my question was, in your Witness Statement, you describe this relevant information to include the firm's "promised and ongoing corrective

870

actions." That's what you say in your Witness Statement?
A. When we are considering issuance of a Warning Letter, yes, we look at all that information.
Q. Okay.
A. Now, having said that, there have been instances where the Agency has not waited for a firm's response to issue even a Warning Letter, just for the record. Just to clarify that.
Q. All right. Thank you.
So, let's talk for a moment about the firm's promised and ongoing corrective actions. Now, is that an informal sort of thing? Is your office content just to have oral discussions about what a firm's ongoing and corrective actions are, or do you expect to see something in writing?
A. All of the above. Firms make promises by phone. Firms make promises by e-mails. Firms make promises by written communications. Firms make promises during inspections. Firms make promises at the conclusion of an inspection.
Q. So for a firm to demonstrate a serious

commitment to corrective action, is that typically done in writing?

A. That's one of the ways it's done. But I just have to mention, in writing in itself is--does not resolve the issue. You have to do what you're saying in writing, and I think that's the primary issue that we're dealing with. You can put many things in writing--and the company that we're dealing with and we're talking about today, Apotex, the issue is not what they put in writing. The issue is what Apotex was doing and what Apotex was not doing and what Apotex has promised and what Apotex did not commit--did not accomplish or did not do even though they promised to do many things. So they did put a lot of things in promise, in writing, but the issue is not what they put in writing. It's what they did or did not do.

Q. And I understand that. But for right now, we're just talking generally about what the practice is concerning firms' "promised and ongoing corrective actions" which you describe in your Witness Statement.

And so my question is, when a firm has an

opportunity to put in writing their promised and proposed corrective actions, what kind of document is that? Is it typically a short document, just kind of a summary of a few paragraphs, or does FDA prefer to see something that is more detailed, perhaps several pages?

A. We do not specify or do not rule in terms of what we want to see. Some companies we just choose to write a letter. Some companies write a letter with information but more detail. Some companies write a letter, information and attachments and exhibits. Some companies, they just make promises. It is going to just depend on the inspection, the nature of the issues, and the significance of the issues.

If you cite a firm for not having process evaluation, you're not expecting necessarily that in 15 days that they usually take to respond, they're going to submit a validation package.

Q. Just give me a moment to just reread what you just said.

So for a validation package, if I understand the answer you just gave, sometimes a firm will take

more than just 15 days to submit a validation package?

A. Sometimes a firm might make a commitment to revalidate the process, the entire process, and that could take months to validate. Does that mean that we place that firm acceptable? Absolutely not, because they have to complete that commitment. How about if the validation promises fails and I put them acceptable?

So some people would just submit a Report. Some people make easy corrections, SOP, if that's the case. But some people will require more time to meet and complete all the commitments that they've made and changes or improvements that they need to implement.

Q. So to come up with a serious proposal for corrective actions, how long do pharmaceutical companies typically take?

A. I cannot say. It just varies. It just varies the nature of the deficiencies, and it varies in terms of the nature of the violations and significance. It varies in terms of the state of control that that company is in.

Q. Now, do you evaluate a company's response

before deciding to take action?

A. Can you define "take action"? Because we evaluate a firm's response before issuance of a Warning Letter. That's what we usually do. We do not necessarily depend only on a firm's response to take any other action, like an Import Alert, which is one of the issues that is being discussed here. We look at a firm's response if it's submitted. If it's not submitted, we do not have that information.

Q. Now, you say you don't depend only on a firm's response to take action like an Import Alert?

A. Yeah.

Q. But do you depend, in part, on a firm's response?

A. If a response is submitted, it's one of the firm's--one of the criterias. Remember, I'm talking about for a Warning Letter issuance. We're stepping away from Import Alert. There's no expectation in terms of placing a firm on Import Alert that we have to look at a firm's response. There's many factors that come into play when we're placing a firm under Import Alert or taking any action.

875

Now, we do look at a firm's response--and that's our policy as of September of 2009, where within the Response for--to a 483 is submitted within 15 days, prior to issuing a Warning Letter, we will take that response into consideration.

Q. How long does it typically take your office to consider a proposed response like that?

A. It's just going to depend. There is no magic number. It's going depend. You have companies with numerous products. You have companies with very few product. You have companies with one or two APIs. And I don't have that information, what time--how long it takes.

Q. Let's take the example of a company that has a hundred different products. How long would it take your office typically to review a proposed corrective plan with respect to that kind of operation?

A. Again, it--a hundred products, there could be sterile products. There could be extended-release products. There could be--it's just going to depend.

Q. 24 hours?

A. Absolutely not.

876

Q. How about a week?

A. I just don't want to put a time frame because it's--there is no magic day on establishing how long would it take.

Q. Now, you also describe the relevant information to include the firm's regulatory history. I'm coming back to your Witness Statement.

A. Yes. Could you refer me to the paragraph?

Q. Yes. It is still Paragraph 20, still that last sentence.

A. Yes.

Q. And that would include whether the firm received a prior Warning Letter; correct?

A. That would include, but it's not limited to.

Q. And that would include whether the firm had prior FDA-initiated recalls; correct?

A. Prior FDA-initiated recall? FDA does not initiate recalls.

Q. You've never heard of a term an "FDA-initiated recall"?

A. FDA does not have the authority to initiate a recall. If there's a Class I recall, there's Advisory

877

Notices that are put out. If there's a Class I recall, there's mechanisms that the Agency would use to contact the firm and try to--but usually FDA, and that's very clear--does not have that authority to require, request a firm to--when we say "require," I say to order a firm to initiate a product recall. And we've tried, but it hasn't been approved by a statute yet.

Q. But FDA has the authority to request a firm to recall product; right?

A. We ask firms--it's not unusual, when we find significant violations, to ask the firm what do they plan to do with the product in the market.

Q. Now, the nature and significance of the violations--I'm coming back to your Statement here--is also part of the relevant information you assess in deciding whether to take action?

A. The nature of the violations is, indeed, one of the factors that we take into consideration.

Q. And that would include whether violations are repeated?

A. Yes, if it's--yes, but not in itself a

878

repetition of a violation in itself is what drives us to take an action.

Q. And it would also include whether repeated violations had been cited in Warning Letters before?

A. Not necessarily. You have--for example, you have the Etobicoke 2006 inspection cited significant violations in that 483, and if you read the EIR, significant issues, significant GMP issues were cited in that inspection. That was in--that was not placed on a Warning Letter.

Does that make them least significant? I don't think so.

Q. If a firm fails to address problems that were cited in a Warning Letter, is that not something that you take into consideration in deciding whether a regulatory action is appropriate?

A. That's one of the factors that we take into consideration, but it's not--if they only failed to comply with the commitments they made on the Warning Letter, what the--something was cited on the Warning Letter and it comes up again. If you have a 483, if you have an Inspection Report where--if you have an

879

inspection where issues, significant issues were discussed, certainly that could be brought up in a Warning Letter. It could be brought up in a 483.

A Warning Letter--just for the Honorable Tribunal, a Warning Letter--we usually issue--sometimes Warning Letters with very short citations, very--four or five citations, three or five citations. We have even sometimes streamlined Warning Letters, and the reason for that, the intention of a Warning Letter is not to list every single violation that we have found in the course of an inspection.

So I just want us to understand that a Warning Letter highlights some examples of the violations that are found but should not be taken as the absolute violation. There's a paragraph in that Warning Letter that puts that responsibility on the facility to address all the GMP violations.

Q. So, Dr. Rosa, Counsel for the United States will have an opportunity to ask you questions after I'm done. So if you can focus on the question that I ask, then things will go a bit quicker.

A. I will try, but I don't want you to make the

880

incorrect assumption if I don't explain something that needs clarification. Okay?

Q. You can count on me not to do that.

Now, you also say in your Witness Statement that a firm's past commitments are relevant information; correct?

A. Again, one of the factors are--past commitments is one of the factors that we look at.

Q. Okay. And this would include whether past cGMP deficiencies had been corrected; correct?

A. Yes.

Q. And whether the firm had lived up to the promises that it made to correct past cGMP deficiencies?

A. Again, that's one of the factors. That's one of the factors that we look at.

Q. Risk to the public health is also relevant to the regulatory action assessment you describe here.

A. Risk to the public health is, again, another factor that we look into when we are looking into possible actions, just another factor.

Q. Now, if a sterile intravenous product

881

contained visible fungal contamination, would this pose a risk to the public health?

A. It may. It may pose a risk. Would we pursue a regulatory action--again, there is other factors that come to weigh, and you asked yesterday about drug shortages, medically necessary drugs. That's one of the factors. Availability of drugs is one of the factors as well.

Q. Indeed, but what I'd like to do is better understand right now what it means, a "risk to the public health." So I'm going to go through a few examples, and I'd like your views on whether this represents a risk to the public health.

Now, if a sterile intravenous product contained visible medical--metal particulate contamination, would that represent a risk to the public health?

A. That may represent a risk.

Q. What if a sterile product was contaminated with endotoxins? Would that be a risk to public health?

A. That may represent a risk.

882

Q. If a drug product contained glass shards, would that be a risk to public health?

A. That may represent a risk as well as fiber, as well as metals, as you mentioned. There's just many other factors and many other contaminants that can represent a risk.

Q. If a sterile product had microbiological contamination, would that be a risk to the public health?

A. That may represent a risk. But you could have non-sterile products with microbiological contamination. You can have non-sterile products that can have particulates and can have metals and can have fibers and can have all sorts of stuff that can also represent a risk.

Q. If products on the U.S. market resulted in actual patient injury, would that evidence a risk to public health?

A. Certainly that may represent a risk, yes.

Q. And something like postoperative fever and chills would be a form of patient injury?

A. I'm not a medical officer to answer.

883

Endotoxin can cause that reaction, but I would prefer that a medical officer talk specific about postoperative effects.

Q. Now, if you had injectable products that were contaminated with fungus or glass shards, would FDA generally require that the manufacturer stop production to resolve the problems?

A. Again, it's going depend on several issues: The drug, the impact of asking the firm to stop production, and the risk--the harm to patient of not having drugs available. So, under certain circumstances, the Agency would have to work with the company, and if that comes to happen, if there's an issue of availability of drugs.

Q. Now, returning to the last sentence of Paragraph 20 of your Witness Statement, this describes the relevant information that it is your responsibility to review; correct?

A. That's one of my--again, when I state it is my responsibility is as Division Director, that--not to be interpreted that I am the one that necessarily looks at every single piece of paper or letter

884

written. I just--so it's my responsibility in that sense.

Q. Yes.

Now, you don't list among the relevant information here drug shortage information; correct? That's not listed?

A. Well, if it's not there, yeah, I didn't list it. But that doesn't mean that that's not done. Actually, it's part of our review of every case. The fact that I didn't list it here, I sat down and I was writing. It is not that I have a--looking for--I wrote statements here, but there is many other things that are not written here that we also do.

Q. Now, is it your responsibility to make drug shortage decisions? I'm using the word "your" to describe "you" personally as opposed to others within the Agency.

A. No. No, it is not. Drug shortage has a unit. There's a unit of drug shortage responsibility to do the evaluation and the assessment of that--of the impact of an action in terms of drug shortage.

So our responsibility is to consult with

885

them. Our responsibility is to use the information. Our responsibility is not to ignore the information. Our responsibility is to, as an agency, make the right decision.

Q. So in terms of your personal responsibilities as Director of the Division of International Drug Quality and the Office of Manufacturing and Product Quality, your responsibility is to assess the compliance issues. It's another part of FDA that assesses the drug shortage issues?

A. Right. The other division, the other unit within FDA is who assesses that part. Again, but it doesn't--the Agency is the largest agency, I think, one of the largest agencies in the world. We do not operate in silos. When we consult with them, they respond to us. We meet. We have discussions. And a decision--there's not a decision of the IDQ. It's not a decision of drug division. It's a decision of the FDA.

When a Warning Letter--whether an Import Alert, it's the FDA--I want you to understand that it is not that we decide on a drug shortage. It is not

886

that even drug shortages decide if--an action. It's the FDA that has that responsibility to assess and evaluate it as an agency, and that's what we do.

Q. And what level within CDER is that decision taken? So, in other words, is the decision taken by the director of the Office of Compliance when there's drug shortages weighing in one direction and compliance issues weighing in another direction, or is that decision taken at a higher level within CDER?

A. If there's a difference between drug shortages and compliance in the way that we're seeing a situation, that--the senior management is involved. At the end of the day, Dr. Woodcock is the ultimate person responsible within the FDA, if she has to make that decision, she'll make it.

But I can--that, I don't recall any incident or any case where a drug shortage decision in itself in terms of taking an action or not has had--that she has had to rule in terms of one way or another because that's part of the discussion. It is actually part of our FDASIA legislation that was passed, that there's an expectation that we discuss, that we consult with

887

drug shortages, and that before taking an action, that that is taken into consideration.
Q. So you referred to the--is it FDASIA legislation?
A. Yes.
Q. You wouldn't remember what that stands for, would you?
A. We have a bunch of lawyers here. Food and Drug Act--I could get you that information in a sec.
Q. When was that legislation passed?
A. That was in July 2012.
Q. Okay. And before that, did things work differently? You referred to that as having some impact on the way that you worked.
A. No. It actually just puts in a legislative piece what we've been doing historically within the Agency. It's like the exchange of inspection information. We have confidential agreements. We exchange information. Now Section 712 allows us to do that formally.
Q. So I'd like to refer you to Paragraph 21 of your Witness Statement.

888

A. Yes.
Q. And here you refer to a number of tools that CDER has to address when firms in the United States or its territories fail to implement permanent and sustainable corrective actions for cGMP violations. Do you see that?
A. Yes.
Q. So I'm just going to go quickly through these different factors you have listed there.
FDA can issue a warning or untitled letter to a foreign facility?
A. Excuse me. Where are you reading, counsel?
Q. Okay. So you've got Paragraph 21, and then below that you have got 1, 2, 3, 4, 5, and it continues on to 6 on the next page.
Do you see that? You have got a list of different things?
A. Okay. I see them. Yeah.
Q. Okay. All right. So FDA can issue a Warning Letter to a foreign facility; correct?
A. Yes.
Q. And it can issue an untitled letter to a

889

foreign facility; correct?
A. Yeah.
Q. FDA can request a permanent or preliminary injunction against a foreign firm; correct?
A. Not against a foreign firm in itself. I don't recall that having been done, with the exception of the Ranbaxy case. And they had a manufacturing facility here in the United States, so ...
Q. The Indian Ranbaxy--
A. Yes.
Q. --directly owned a manufacturing facility in the United States? Or are you thinking--
A. There's a manufacturing facility--
Q. It's better for you to wait for me to finish my question because that way you know what you're answering before you can give your answer.
A. Okay.
Q. So you're saying that the Indian company Ranbaxy directly owned a facility in the United States, and it was not owned, instead, by the U.S. subsidiary of Ranbaxy?
A. No. I did not say that at all. I said that

890

Ranbaxy has a manufacturing facility in the United States. That's all I said.
Q. But you do recall that FDA did obtain a permanent injunction against Ranbaxy in India?
A. There's an injunction including in their facilities, and a consent decree to which they agree to include the Indian facility in that injunction.
Q. FDA can request that drugs in the United States be seized even if they're produced by a foreign facility; correct?
A. Yes. If it--once it becomes--yes. Yes.
Q. FDA can withdraw--excuse me.
FDA can withdraw approval of drug applications owned by foreign firms; correct?
A. Yes.
Q. FDA can seek criminal sanctions against a foreign firm; correct?
A. Not that I--against a foreign firm. We don't have jurisdiction in a foreign country to go and prosecute somebody in a foreign country.
Q. In the Ranbaxy case, were there criminal sanctions against Ranbaxy?

A. There was criminal sanctions. There is nobody indicted as such, is there a person indicted in the Ranbaxy case.

Q. I'm not referring to--just to be clear, I'm not referring to individuals. What I'm referring to here is the foreign firm itself.

So my question, just to repeat it, was, FDA can seek criminal sanctions against a foreign firm; is that correct?

A. FDA can investigate. I won't say they can seek criminal, although--yes, the Agency can seek. That doesn't mean it's going to be necessarily approved because there are so many factor from a legal term--legal perspective that needs to be--to come into play in order for that to get approved anyway.

Q. FDA can request that a foreign firm recall drugs from the market; correct?

A. As I mentioned before, FDA does not have authority to order a firm to recall. A recall is a voluntary action from a firm.

Q. And so FDA can't ask a firm to recall product?

A. We usually do not formally--we do not normally ask a firm to recall a product. We lay the issues, the deficiencies. We ask them--we have concerns about products that are in the market, but the decision to recall a product relies on the company.

Q. So does that mean that FDA can ask a U.S. firm to recall product, but it can't ask a foreign firm to recall product?

A. The same thing that applies in that sense--what I mentioned in my earlier statement--to domestic would apply to foreign. If there's a foreign firm making adulterated drugs, if there's a local domestic firm making adulterated drugs, the Agency can ask the firm about their intentions in regards to the product that remains in the market. The Agency usually does not specifically ask a firm to recall a product.

Q. So could you take a look at the last item in Paragraph 21 where you say that among CDER's available tools is "requesting that the firm voluntarily recall a drug from the market"?

A. Right.

Q. So could you--

A. That's what I mean.

Q. --explain that statement?

A. That's what I mean. Requesting that a firm voluntary recall, what I'm meaning with that statement is that we will have a conversation with the firm, we will explain the issues to them. We will ask them what are their intentions with regards to the product that is in the market. What do they plan to do with the product in the market.

A company can say, "I do not--and I will not recall." The Agency cannot tell them they have to recall because we don't have that power to do so. So what I mean with the statement is that the Agency will try to work with the company to voluntarily initiate that action, but FDA cannot--has no authority to require--to order, I should say, a firm to recall product from the market.

Q. All right. Thank you for that explanation.

And that authority to request in the way that you've just described applies both to foreign firms

and to domestic firms; correct?

A. That we do not have the authority to order applies to both.

Q. But you can, in the diplomatic way that you've described, ask a firm--

A. What they plan to do with the product in the market, yes.

Q. Okay. I'd like to turn to Paragraph 23 of your Witness Statement.

A. Okay.

Q. Okay. So in the second-to-last sentence you state that FDA does not give advance notice of an Import Alert for cGMP violations, so the firm does not have the opportunity to flood the U.S. market with adulterated drugs before the Import Alert takes effect.

Do you see that?

A. Yes.

Q. In your experience, have you ever seen a major pharmaceutical company attempt to flood the market with adulterated drugs in advance of an Import Alert?

09:41:57 A. I do not--the Agency does not have the mechanisms to monitor if a firm--

PRESIDENT VEEDER: Can I stop you? Sorry.

THE WITNESS: Yes.

PRESIDENT VEEDER: As counsel has reminded us all, he's short of time. So if you could try and answer the question directly first and then obviously add by way of clarification.

THE WITNESS: Okay.

PRESIDENT VEEDER: It might help if you just answered yes or no, if you can do that, and then add what you want to add.

THE WITNESS: Okay.

BY MR. LEGUM:

Q. Do you want to hear the question again?

A. No. I remember.

The Agency--I do not recall seeing a flood in the market of product of a company that is to be placed on Import Alert.

Q. I'd like to now turn to Paragraphs 27-29 of your Witness Statement where you talk about the 2006 Etobicoke inspection. Now, we've already established

09:43:00 that you had no role in that inspection.

In Paragraph 26, you state that in 2009, Hidee Molina reviewed Apotex's inspection history. Do you see that?

A. Yes. She was one of the compliance officers looking at the case.

Q. She prepared a summary, a short summary of the Apotex case in March of 2009?

A. I cannot recall. Do you have the document that I can see?

Q. I do.

A. Okay.

MR. LEGUM: So could we please distribute Exhibit C-486 which is in the Joint Core Bundle at Tab 14.

THE WITNESS: Yes.

BY MR. LEGUM:

Q. So you relied on the summary that she prepared in discussions with your superior, Mr. Edwin Rivera-Martinez; correct?

A. I received a summary and, yes, I looked at the summary and discussed it with Edwin Rivera.

09:45:14 Q. Okay. Now, Ms. Molina did not mention the 2006 Etobicoke inspection in her Apotex case summary; correct?

A. I don't see it referenced here specifically, but there's a date of December of 2006 in the first paragraph. So that certainly is an indication that information from 2006 was, indeed, reviewed at some point.

Q. I'm sorry; I see a reference to 12/10-19/2008 in the first paragraph.

A. The second paragraph, "We have received approximately [redacted] consumer complaints and [redacted]," and it continues reading, "since December of 2006."

Why would a December 2006 date be used if at some point information from 2006 may have not been reviewed?

Q. I'm sorry; I wasn't referring to--my question was, did she refer in this summary to the 2006 Etobicoke inspection, not to information concerning consumer complaints and Adverse Event Reports.

A. Right. And I said that information specifically on the inspection is not referenced here.

09:46:46 Q. Okay. Do you remember that in June of 2006 you wrote to Mr. Famulare--

A. Excuse me. June 2006?

Q. Did I say June 2006? I'm sorry about that.

Do you remember that in June 2009 you wrote to Mr. Famulare about Apotex in something that in this arbitration has been referred to as a "Key Issues Document"?

A. Can you refer me to the document? I wrote to Joe Famulare many things.

Q. Yes. It is Exhibit C-358, which is in the Joint Core Bundle at Tab 16.

ARBITRATOR ROWLEY: 1s this 16 or 6-0?

MR. LEGUM: 16.

BY MR. LEGUM:

Q. So take a look at that, and the question that I'll ask you about it is, you did not discuss the 2006 inspection of Etobicoke in your memo to Mr. Famulare; correct? That's my question.

A. There is no statement in this document. There is no statement in this document about the 2006 inspection. The subject of the document is

899

09:49:12 "Additional Information Requested on Apotex," so perhaps this memo is in response to specific information that may have been requested and not necessarily given--intended to give an overall summary of the company's history.

Q. The Etobicoke Warning Letter from June 25, 2009, also did not mention the 2006 Etobicoke inspection; correct?

A. I don't know by memory, but it may or may not have included information from 2006.

Q. All right. I can show you the document, but if you assume with me--because I can represent that it does not have any reference to the 2006 inspection--why is it that, although in the documents from 2009 concerning enforcement action or advisory action against Apotex for the Etobicoke Warning Letter, why is it that there is no reference to the 2006 inspection as being important, but you devote several paragraphs to it in your Witness Statement?

A. I can easily explain that, counsel. The fact that it is not written in a document does not mean that it was not discussed. The Agency has many

900

09:50:46 meetings, many discussions prior to initiating an action. And I can tell this Honorable Tribunal that we do discuss previous history prior to initiating any action. The fact that you may not find it on the Warning Letters you reference or in this particular memo does not mean that that discussion did not happen.

Q. Are there any other documents that you can remember from that period where there's mention of the 2006 inspection?

A. I cannot say from the top of my head. I cannot say. But in the same way I trust your statement that it doesn't include it, I am saying under oath here that that's part of every review that we do.

Q. All right. Apotex proposed Corrective Actions in response to the Form 486 for the 2006--

A. 483?

Q. Let me do that again.

A. Okay.

Q. So Apotex proposed Corrective Actions in response to the Form 486 for the--

901

09:51:52 A. 483.

Q. Didn't I say 483?

A. No.

Q. Okay. Let me try that yet one more time.

A. Okay.

Q. Apotex proposed Corrective Actions in response to the Form 483 for the 2006 Etobicoke; inspection; correct?

A. They submitted Corrective Actions, yeah.

Q. And in the 2008 inspection, the inspector confirmed that the Corrective Actions for the previous 483 given to the firm had been reviewed and that she found no deficiencies; is that correct?

A. I don't have that report in front of me.

Q. You don't remember that?

A. I would prefer the Report--if she said it and it was in the Report, then I would have to say that what she said is correct.

Q. Was that something that you took into consideration as well in your decisions in 2009 as to advisory action with respect to that facility?

A. Did I take into consideration her statement

902

09:53:06 or did I take into consideration that they made commitments to correct?

Q. Both.

A. We took into consideration everything that was available to the Agency.

Q. Now, you don't mention the corrective actions taken by Apotex in response to the 2006 Etobicoke inspection or the inspector's findings as to whether those corrective actions had been implemented in 2008. You don't discuss that in your Witness Statement. Is there a reason for that?

A. No. I just didn't--I didn't think that I needed to include everything I was thinking about in a Witness Statement. So--I did say in the Witness Statement that we looked at the firm's history. That includes Apotex. That includes every company that we review.

Q. I'd like to move on to Paragraph 55 of your Witness Statement.

A. 55?

Q. Yes. And the sentence I'll ask you about is the one that says, "As with the 2006 and 2008

903

09:54:36 Etobicoke inspections, Apotex had failed to submit Field Alert Reports for quality defects found in drug products manufactured at the Signet campus site."

Now, it's not correct that Apotex never filed Field Alert Reports for that site, is it?

A. I don't have the reports in front of me, but the citations about Field Alert Reports is in that--in those EIRs. We would have to look at those EIRs and see the details of those inspection reports, and then make a determination they did fail to file.

Failing to file a Field Alert within three days is a failure to file a Field Alert Report. If you submitted it and you filed it a year after, you failed to file that Field Alert Report when you were expected to.

Q. So from your office's perspective, there is no difference between a firm that never, ever files a Field Alert Report and one that files it four days after the event?

A. Four days?

Q. Yes.

A. I don't recall that we have made a--had a

904

09:55:59 discussion on four days of a Field Alert Report involving Apotex. I'm trying to understand your question. The difference between--I think what we need to explain is the importance of a Field Alert Report.

Q. And we can come to that in a moment.

A. Okay.

Q. But what I'm trying to do is to understand the answer you gave to my previous question where you said that a failure to file a Field Alert Report within three days is a failure to file a Field Report.

A. Right. And that's correct.

Q. And so my question to you is, qualitatively, from your perspective, are you saying there is no difference between failure ever to file a Field Report and filing a Field Report three days or one week late?

A. I'm saying that it's a violation to the regulations to not file it in three working days. If you file it in four, which is not the case, if you file it in six months, it is still a violation. And the purpose of a Field Alert Report--the Field Alert Report is one of the most important mechanisms and

905

09:57:02 tools that the FDA has to obtain information about the quality of the product that was approved.

Q. So in making regulatory decisions, decisions about whether to take regulatory action, something that you do not take into consideration is whether a Field Alert Report was filed five or six days late or whether it was never filed at all? That's not something that enters into your calculation?

A. I don't recall that--the issue is they're violating the regulation. They're not submitting it in three days. They're not submitting it in three days is a violation to 314.81. That's--if they submit it in 5 days, 10 days, the Agency will then have to discuss and make a decision how significant it is based on the actual nature of the issue being reported. I will not say it's okay to filed a field report in four days. It is still a violation to the regulations.

Q. I'd like to now have you take a look at Exhibit C-373, which is in the Joint Core Bundle at Tab 27.

Dr. Rosa, this is an e-mail from August 18,

906

09:59:28 2009, from Joseph Famulare to Murray Lumpkin, attaching what appears to be called the Sharfstein Report.

Now, could you just explain to us what a Sharfstein Report is?

A. A Sharfstein Report, at the time, was just a report to inform senior management of any potential action being considered. And the reason of that Report was that very often our senior managers were bothered by the press or by many people about a Warning Letter, an Import Alert, or an Action, and they had no information regarding that Action.

This Sharfstein Report was just a summary, is there any action or anything going on in compliance and in other offices. It's just--this was not limited to the Office of Compliance--that they can be asked about. And as you know, any Warning Letter is posted, any action of an Import Alert, any--any placing a firm on Import Alert is--becomes a public event. So they didn't want to be caught off notice in that sense to not be in a position to respond, at least to know that that had occurred.

907

So, Sharfstein implemented, you know--I believe it was a weekly or every-other-week report of any upcoming events that he needed to be aware of.

Q. Now, at the bottom of this report, there's a field where it says "Known/suspected injuries" and then "Firm: Apotex"?

A. Right.

Q. And there's nothing that's listed there?

A. Right.

Q. That's the place where ordinarily you would list whether there were known or suspected injuries; correct?

A. If the person submitting the Report knew about any suspected or known injuries, that would be included there.

Q. I'd like you to ask you to take a look at Exhibit C-503, which will be handed out to you.

MR. LEGUM: And this is not in the Joint Core Bundle. So I can't give you a reference.

BY MR. LEGUM:

Q. Why don't you take a moment to review this document, and I'll simply say for the record, that

908

it's an e-mail chain that begins with an e-mail from Rick Friedman to Edwin Rivera-Martinez and yourself, Dr. Rosa, dated the 22nd of June, 2009, with the subject being "For Clearance, Apotex Info Advisory: Due 6/19."

So take your time to look through it and let me know when you're ready to answer questions.

A. Okay.

Q. So first, what is an "info advisory"?

A. An advisory--again, this is a question that the press office should be the one that would normally respond, but this is a mechanism or an announcement that the Agency will make in regards to an event or something that could be of public interest, an advisory communication.

Q. So this concerned an info advisory that was being prepared about the Apotex case; correct?

A. I would say, yes, there was an advisory document being prepared in case that it was needed to be published. And an advisory is not necessarily published by default when an agency takes an action. Many times an advisory--

909

Q. Dr. Rosa--

A. Yes.

Q. Your counsel can ask you follow-up questions on it, but if you wouldn't mind focusing on the question, we'll get out of here much quicker.

A. Okay.

Q. So this was being prepared for a draft info advisory?

A. In the case that it was needed.

Q. That's right.

Now, in Mr. Friedman's e-mail to you and Mr. Rivera-Martinez, he says "The below is sample language that we can use for the Apotex advisory to address the quality of products on the market."

A. Okay. I see it. Okay.

Q. That's the top e-mail. Do you see that?

A. Yes, I see it.

Q. And then below that is the--an e-mail from Debra Autor to Mr. Friedman, Mr. Famulare, and Ms. Maroney-Benassi that has a statement concerning Caraco.

Do you see that?

910

A. Yes.

Q. The language that Ms. Autor was mentioning concerning Caraco, she was proposing that that be used--with modifications, obviously--in the info advisory for Apotex; correct?

A. That appears to be the case, yeah. I'm not familiar with Caraco, so I can't say what language was or not used with the Caraco case.

Q. Understood. But what I'm asking you is that when you received this e-mail, your understanding was that Ms. Autor was saying that we should use, for Apotex, this same language that we're using for Caraco, but obviously you shouldn't say "Caraco," you should say "Apotex" instead?

A. I don't recall saying anything. I don't see myself writing. If you can refer me to--when you're saying that I said, I don't...

Q. Actually. I wasn't asking you about a statement.

A. Okay.

Q. So you received this e-mail from Mr. Friedman?

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A. I was cc'd. Let me see. Yeah, I would receive it from Rick Friedman on the 22nd, but it was addressed to Edwin.

Q. And was it you that was preparing the info advisory, or it was Mr. Rivera-Martinez?

A. No. I don't recall myself preparing directly an info advisory. I don't recall me preparing it.

Q. But your understanding was that Mr. Friedman was saying that the information for Caraco should be included in the Apotex info advisory?

A. Well, I see that Mr. Friedman is saying that this is what we said in the Caraco, but I can't speak to what his intentions were. But it says, "At present, the FDA has no evidence that Caraco product"--so he's talking about Caraco. I cannot say what his intentions were in terms of including or not. It's--I can't. It will be improper for me to do so.

Q. Okay. Let's talk about the statement that you just referenced, which says, "At present, the FDA has no evidence that Caraco products currently on the market are not safe and effective. If the FDA identifies Caraco drugs on the market that pose risks

912

to patient safety, the Agency will take appropriate additional regulatory action and immediately notify the public."

Do you see that language?

A. Yes, I saw that.

Q. Now, at the time that this note was being written, it was correct that the FDA had no evidence that Apotex products currently on the U.S. market are not safe and effective; correct?

A. FDA had evidence that Apotex's products were adulterated. FDA had evidence that the products were being rejected. FDA had evidence that the firm was not operating in a state of control.

Q. So, let me repeat my question, which didn't get to whether FDA believed that drugs did not meet cGMP but, rather, whether they were safe and effective. Okay?

So the language here is "FDA has no evidence that Caraco products currently on the U.S. market are not safe and effective."

My question to you is, at the time this was written, FDA had no evidence that Apotex products

913

currently on the U.S. market were not safe and effective?

A. FDA had evidence that people were--there was complaints about Apotex's product. If that can be translated into the product being--were not safe and effective, we would have to see each and every one of those complaints. But I cannot say that Apotex's products were not safe and were not effective or were safe or effective. I'm focusing on Apotex's GMP violations that made the drug products adulterated.

Q. And so Debra Autor was the director of the Office of Compliance at the time; correct?

A. Yes.

Q. So Ms. Autor was saying that FDA should say to the public that, at present, FDA has no evidence that Apotex products currently on the market are not safe and effective.

If she was saying that, you disagree with that proposition? You disagree with her on that?

A. No. I'm just saying I don't have information about Caraco. So I cannot say--she's making that statement, "at present, FDA," so I'm assuming that FDA

914

had no information based on what she's saying here, but I personally cannot say--because I didn't see. I'm not familiar with that case.

Q. Right. But you see that the heading of her e-mail is not one that refers to a Caraco info advisory; it is one that refers to an Apotex info advisory.

A. Yes.

Q. And she begins it by saying, "By the way, this is what we said re Caraco." And then in her preceding e-mail, the one of 9:40 p.m., she says--she refers to additional points that need to be added to the info advisory.

Do you see that?

A. Yes.

Q. And going to the top e-mail, from Mr. Friedman, he says "The below is sample language that we can use for the Apotex advisory to address the quality of products on the market."

A. I'm trying to understand the question.

Q. I was coming to the question, actually.

A. Okay.

915

Q. So the question is, are you saying that you do not understand this e-mail to be referring to Apotex?

A. I'm saying that--no, I have not said that at all. I said that I do not have any information about Caraco. I'm not--I'm not even writing this e-mail, so I'm actually not saying anything. It's not uncommon in the Agency--and I would assume in any other organization, that when--

Q. Mr. Rosa--

A. Just let me, Counsel, because--

Q. Please go ahead.

A. A few minutes ago I was going to explain the purpose of the Field Alert Report, and we didn't do that. So I just don't want us to misinterpret.

It's not uncommon to use a template or use information that was already previously used for a statement to be repeated if the issues are similar. So I think this is just an e-mail saying, "let's not reinvent the wheel. If there's some similar issues, similar language we can use," that's what this e-mail is about. It's not about the safe and effective.

916

It's not about--this is an e-mail. They're talking about we can use this information, yes or no. And that's what I'm seeing in this exchange of e-mails.

Q. Thank you.

Let's move on to a different topic. This is Paragraph 61 of your First Witness Statement.

A. We're not going to use this any longer, I assume? I'll put it on the side, right?

Q. Yes, please. I'm sorry about the mess.

A. No, that's fine. Paragraph 61?

Q. That's the one. So take a moment to reread it just to refresh your recollection.

A. Okay.

Q. Now, you state that you reviewed and cleared the draft Import Alert recommendation on August 19, 2009; correct?

A. I'm trying to find that sentence. I'm sorry.

Q. It's in the middle.

A. Okay. "I reviewed and cleared the draft Import Alert recommendation." Yes.

Q. Okay. So the next sentence--in the next sentence, you state that "This recommendation was

917

based on the Signet 483, the EIR, and other evidence from the Etobicoke 2008 inspection (which shared its quality system with the Signet campus site), as well as CDER's August 17 discussions with the firm."

Do you see that statement?

A. Yes.

Q. Now, was the recommendation based on other things?

A. The recommendation for an Import Alert, is that what you mean?

Q. Yes.

A. The recommendation for an Import Alert takes into consideration several factors. We talk about the firm's history. We talk about the firm's ability to comply and correct violations. We take into consideration past commitments. We take into consideration the seriousness of the issues. We take into consideration drug shortages. We take into--the availability of drugs. There's--the type of products, amount of products, that goes into that process of drug shortage review in the case, but--the consult.

So those are the things that we take into

918

consideration, among other things.

Q. And in this sentence you're describing the documents that you relied on in making that decision; right? The 483, the EIR, other evidence from the Etobicoke 2008 inspection.

Was there anything else that you thought that was important?

A. Yes. I think the most relevant--

Q. In terms of documents?

A. I'm sorry?

Q. In terms of documents?

A. In terms of documents? Yeah. The most relevant is the deficiencies cited on the 483; the EIRs; the previous EIRs, those are in documents; commitments made by the company, those are in documents; uncorrected violations, those are all in documents.

This is not intended to be an all-inclusive list. These are just statements that I made. But again, there are so many factors that come into play when we're looking at a case, I'm just--I reviewed a draft Import Alert, and this recommendation was based

on 483 and other evidence from the 2008, which shared quality system, and I keep--does this mean that this is the only thing I look at to put in an Import Alert? Absolutely not.

Q. So why did you list these?

A. Why did I list them? Because those were the ones that came to my mind when I was writing the Statement.

Q. Okay. Now, you referred to uncorrected violations.

A. Yes.

Q. Can you tell us what you have in mind by that?

A. Uncorrected violations? In 2006, there was an inspection in Signet where there was one citation at the Signet facility, one citation written by Monica Caphart, where they cited one violation regarding potential cross-contamination issues at the facility. One violation.

In 2008, the Signet inspection again found that that had not been completely addressed. There was other verbal observations in that 2006 inspection,

2008, had not been clearly addressed.

Q. Now, the review that you refer to here, it doesn't mention Apotex's response to the Etobicoke Form 483; correct?

A. No. For an Import Alert? No. It doesn't include it, no.

Q. So that wasn't something you took into account?

A. We didn't have that available at the time, and--

Q. The Response to the Etobicoke commitment?

A. Oh, Etobicoke, I'm sorry. To Etobicoke, yes.

Q. Okay. So you didn't mention that, but that was something that you took into account?

A. We look at entire history, the entire package, at the time, and we look at all the information the Agency has available prior to taking an action.

Q. Now, you also don't mention here Apotex's response to the Etobicoke Warning Letter; correct?

A. No. Again, this not an all-inclusive list.

Q. Now, at the time that your decision to

recommend the Import Alert was made, FDA had not completed its review of the Etobicoke Warning Letter; correct?

A. FDA had completed its review--and you're going to show me a document, and that's fine. The fact that it wasn't closed in CMS, completely closed, does not mean that we had not looked at everything we needed to look at.

Q. Now, what does "closed in CMS" mean?

A. CMS is our database where we assign cases and we close cases. That is our database.

MR. DALEY: Counsel, I'm sorry to interrupt. Your last question actually said that FDA had not completed its review of the Etobicoke Warning Letter. I assume you mean the Response to the Etobicoke Warning Letter.

MR. LEGUM: Absolutely.

BY MR. LEGUM:

Q. And if that's what you understood as well--

A. Yes, the Response, yes.

Q. Who writes the Sharfstein Reports?

A. The Sharfstein Report? Whoever has the

information within the office. We have multiple meetings a week, and a compliance officer could have information. The team leader could have. Whichever unit has the relevant information that may be useful for Sharfstein at the time would be responsible for writing it. And senior management would, perhaps, look at it and ask questions and then send it out. It's a very short paragraph. It's not necessarily a huge report, it's just a brief summary.

Q. So you write them yourself sometimes?

A. No. We don't write them anymore. That was when Sharfstein was the Acting Commissioner. So he wanted to see those type of reports. Now, Dr. Hamburg does not require a Sharfstein Report. He's no longer with the agency. So that was something that, at the time, when he was acting as commissioner.

Q. So my question was at that time, back in 2009, you wrote Sharfstein reports yourself sometimes?

A. No.

Q. You did not?

A. No. I would provide information. I don't recall ever--I don't recall writing a report. That

923

wasn't my responsibility. That was managed by the Office of the Commissioner, but it was more channeled through the different offices who had the information that would send it. So it was called the Sharfstein Report. So our immediate office, we had--the CDER Office of Compliance, OMPQ, or immediate office would be responsible for gathering that information and forwarding up to Dr. Sharfstein.

Q. So let's take a look at an exhibit that should already be in front of you somewhere, which is C-373, the Joint Core Bundle at 27. It says C-373 at the bottom. It's the e-mail from Joseph Famulare of August 18, 2009, to Murray Lumpkin.

A. This one? Thank you.

Q. So if you look in the second paragraph, it says, towards the middle, "response to WL received 8/4; currently under review."

A. Right.

Q. "Inspection of the other Apotex sites completed 8/14. ORAOC covered all the firm's products," et cetera.

So this had obviously been updated recently

924

because it refers to "inspection of the other Apotex sites completed 8/14," and this is an e-mail dated August 18; correct?

A. And the question is? I'm sorry. I was reading the e-mail. I'm sorry.

Q. Okay. So the question was this had obviously been updated recently since it refers to the inspection of the other Apotex sites completed 8/14; correct?

A. Yeah. This appears to have. Yeah, it has a statement there, "inspection of the other sites completed."

Q. So your testimony is that, although it says in the preceding sentence "response to WL received 8/4; currently under review," you're saying that although this document had been recently updated, that's not accurate?

A. No. I'm saying that when we say something is "under review," that can mean that the case was--the information was actually reviewed, but there's many other aspects to it. When a firm--and I'll give you just one example, too, and I know it can sound a bit

925

confusing, but when we get an inspection report--or when we do not get an inspection report from the field, if I receive that inspection report in my office or not receive it, we will still say that is under review. Although it does not mean that I am or my office is directly reviewing it. It could be ORA reviewing it. There is many other.

So when it's under review, it is considered an open in CMS. It hasn't been closed. So still considered under review in that sense. But the information that was needed to be extracted or reviewed from that correspondence was already evaluated.

Q. Thank you, Dr. Rosa.

A. Okay.

Q. Let's turn to Paragraph 66 of your Witness Statement.

A. 66 or 62?

Q. 66.

A. 66. Sorry. Okay.

Q. Now, you state that CDER found Apotex's September 3, 2009, response "inadequate and lacking in

926

sufficient corrective action"; correct?

A. That's what the Statement says, yes.

Q. I'd like you to take a look at Exhibit C-525, which is not in the Joint Core Bundle.

A. Okay.

Q. So this is an e-mail from Lloyd Payne to Hidee Molina dated October 28, 2009.

A. Yes.

Q. And Lloyd Payne was the lead investigator of the Signet inspection; correct?

A. Yes.

Q. And he states that Apotex's intended corrections appear to be sufficient for both of the observations that he made; correct?

A. It says for "both observations." I assume those are the ones he made, I guess is what you're saying.

Q. All right. I'd like you to take a look at exhibit C-526, please, which is also not in the Joint Core Bundle.

A. Okay.

Q. Now, this is an e-mail dated November 24,

927

2009, from Hidee Molina to yourself and Mr. Jaworski regarding Apotex submitted protocols.

Now, she refers here to two protocols. Are you familiar with those two protocols?

A. I don't recall them. I know that--yeah, there was protocols that were sent for--to the Agency.

Q. And these protocols were prepared in response to FDA's observations in order to correct the cGMP deviations FDA noted; correct?

A. This Protocol was submitted, as I recall, in response to the deficiencies, in response to the August 17 conversation, in response to placing them on the Import Alert, in response to the fact that they were told that their products were adulterated and that we had concerns with their products. This was on November 24. Many things occur by November 24. This was in response to many things. This was not necessarily--and I'll have to see the specific dates in which this was received if it was received or not in September or was received, but I don't have that information. But this was in response to many, many things.

928

Q. You do recall that as part of Apotex's proposed Corrective Action Plan, it proposed to submit to FDA two protocols: One that addressed the quality systems and one that assessed the quality of product currently in the U.S. market. You do recall that?

A. I recall that we discussed requesting these protocols. I believe, if we're referring to the same protocol, the protocols prepared by Lachman--Lachman Consulting--if these are the protocols prepared by Lachman, those are protocols were, indeed, requested through discussions or meetings that we had with Apotex.

Q. All right. So as I understand it, there were two protocols, one was prepared by Lachman that addressed Product Quality Assessment, and the other was prepared by Jeff Yuen's firm on quality systems. Does that refresh your recollection?

A. Yes. And Jeff was in one of the meetings that we held.

Q. Okay. So in this e-mail that is Exhibit 526, Ms. Molina says to you and Mr. Jaworski, "Just to inform you that I reviewed both the Quality Systems

929

Assessment of Apotex Inc. Protocol number" such and such and the revised Product Quality Assessment of Apotex Inc. Drug Product Protocol number" such and such. "Based on my review, both protocols appear to be adequate to capture both cGMP systems gaps and product that may potentially fail quality attributes."

Do you see that?

A. I see that statement of November 24.

Q. And it's your understanding that Ms. Molina found, based on her review, that both product protocols appear to be adequate to capture both cGMP system gaps and product that may potentially fail quality attributes?

A. Ms. Molina does state that based on her review they were found adequate.

Q. Now, turning to Paragraph 69 of your Witness Statement. Sorry about that. You state that, Apotex did not dispute or challenge FDA's decision; correct?

A. Right. To place them on Import Alert.

Q. But, in fact, to--to place them on Import Alert?

A. Yes.

930

Q. In fact, Apotex did challenge a number of the specific observations that you relied on in recommending that the firm be placed on Import Alert; correct?

A. Apotex disagreed with some of the violations--or some of the citations, yes.

Q. Turning to Paragraph 77.

A. Okay.

Q. You say towards the bottom of the page in the last sentence that "Apotex was re-inspected sooner than other firms with cGMP violations."

A. Yes.

Q. Can you please take a look at Exhibit C-573 which is also not in the Joint Core Bundle.

A. Yes.

Q. This is a priority inspection request for Teva's Jerusalem facility dated May 26, 2011; is that correct?

A. Yes, that's correct.

Q. And the inspections in question were finished in June 2011. Is that your recollection?

A. That appears to be correct.

931

10:33:38 Q. So that's less than one month later, or about a month later?
A. A month later from what? From the memo?
Q. From the request.
A. Yes. That's what it appears. I don't have the date of the inspection. If you have it and confirm that, I would appreciate that. I'm not sure where that date would fall on this memo.
Q. Sure thing.
MR. LEGUM: So can we show the witnesses Exhibit C-332, which also is not in the Joint Core Bundle.
MR. DALEY: Excuse me, counsel, I'm sorry to interrupt. I'm not sure I have the right copy of C-573 that was handed out. I have a document that was handed to me as C-573, which is dated 26 May 2011.
MR. LEGUM: That is C-573.
MR. DALEY: That is the right one? And your question was inspections were committed in June of 2011?
MR. LEGUM: Yes. Give me a second just to read your question. Unfortunately, the way--let me

932

10:35:04 back up a moment.
What you have in front of you is a printout of a spreadsheet of foreign inspections that the FDA provided to us. Unfortunately, the printout cuts off the--part of the page number. So, Mr. Daley, C-573 is the document that's in your hands.
The document that has just been passed out is C-332. But, unfortunately, it is not a good copy. Do you not have that?
MR. DALEY: I do not have that.
MR. LEGUM: All right. I'm going to come back to this later when we have better copies.
MR. DALEY: I'm sorry to interrupt. I just want to make sure I have all the documents.
PRESIDENT VEEDER: Just put the date on the assumption that it's correct.
MR. LEGUM: Okay.
BY MR. LEGUM:
Q. So the date that appears in the spreadsheet for Teva Jerusalem is June 19, 2011.
A. Okay.
MR. DALEY: I'm sorry, Mr. President. I

933

10:36:00 don't have the document that this Witness is being asked about. It would be very helpful to--
PRESIDENT VEEDER: He's not going to be asked about it, but you should have C-332. Do you have that?
MR. LEGUM: No, we ran out of copies.
PRESIDENT VEEDER: Borrow mine.
I don't think he's going to be asked about it because none of us can find the right page.
MR. LEGUM: We have the right page. It is just the month and day is cut off in the copy on the side, which makes it very difficult to specify the month and day based on this copy.
(Discussion off microphone.)
BY MR. LEGUM:
Q. Right. So the date that appears in the exhibit is June 19, 2011.
A. Okay.
Q. Which can be confirmed by looking at the version of this in the record.
So, Dr. Rosa, does that accord with your recollection that Teva Jerusalem was re-inspected

934

10:37:12 within a month of the request for re-inspection?
A. Assuming that the information is correct, yes.
Q. Okay. All right. Let's move on to your Second Witness Statement. Do you have that in front of you, your Second Witness Statement?
A. Yes, I have it here.
Q. I'm going to start with Paragraph 6.
A. Okay.
Q. Just so, you know, we're coming up on our coffee break in about five minutes.
A. Yeah. I would appreciate that.
Q. Of course. Would you prefer to take a break now?
A. No, no. I'm a heavy coffee drinker, so when you mentioned the word "coffee"--
PRESIDENT VEEDER: It's up to you. You can have a break at any time.
THE WITNESS: I can go for another question or two.
PRESIDENT VEEDER: Really five minutes?
THE WITNESS: Five minutes will be fine. I

935

can go for five minutes. Thank you.
BY MR. LEGUM:
Q. All right. In this paragraph, Paragraph 6 of your Second Witness Statement, you state that drugs manufactured at non-cGMP-compliant facilities such as Etobicoke and Signet are deemed to be adulterated by statute.
Do you see that statement?
A. Yes.
Q. Now, that applies to all facilities that FDA finds significant cGMP deficiencies at?
A. Yes. That would be--not compliant with cGMPs would make the products adulterated by definition.
Q. So FDA inspected Teva's facilities at Irvine and Jerusalem and found them to be cGMP deficient; correct?
A. Yes, there were some cGMP deficiencies cited there, yes.
Q. So their drugs were legally adulterated?
A. Their drugs were adulterated under the definition, yes.
Q. And that's true of Sandoz's three facilities

936

which FDA inspected in--2010? 2011?
A. 2011.
Q. That's also the case?
A. Yes. For the ones they received Warning Letters, that's what you're referring to, I would assume, yes.
Q. So if the facility received a Warning Letter, then the drugs are legally adulterated by statute?
A. That's part of the first paragraph in the Warning Letter.
Q. Okay.
MR. LEGUM: All right. Why don't we take a break now, then.
PRESIDENT VEEDER: Let's break. We'll come back at 5 to 11:00.
MR. LEGUM: Thank you.
PRESIDENT VEEDER: Please don't discuss the case away from the Tribunal.
THE WITNESS: Thank you.
(Brief recess.)
PRESIDENT VEEDER: Before we start, I'm going to ask the Secretary something I forgot to ask him to

937

do at the beginning, which is to announce the times for yesterday. If there is any dispute about this, we need to hear about it before the end of today; otherwise, these times will be considered to have been agreed by the Parties.
Please.
SECRETARY TAYLOR: I'm going to go through the aggregate times and then do a more detailed setout of the examination times.
So for Day 3, housekeeping procedural matters, the Tribunal had 20 minutes and 21 seconds.
For the Claimants' Case-in-Chief, 45 minutes and 26 seconds; and the Tribunal had 11 minutes and 36 seconds for questions.
The Respondent's Case-in-Chief, there was 2 hours, 18 minutes, and 22 seconds; and the Tribunal had 9 minutes and 58 seconds for questions.
For the examination of Ms. Debra Emerson, the Respondent had 9 minutes, 36 seconds; the Claimants, 35 minutes and 6 seconds; the Tribunal, 7 minutes, 19 seconds.
For the examination of Mr. Lloyd Payne,

938

Respondent had 5 minutes, 12 seconds; the Claimants, 1 hour, 7 minutes, 11 seconds; the Tribunal, 17 minutes and 4 seconds.
For the examination of Mr. Michael Goga, there were 4 minutes and 43 seconds for the Respondent; 15 minutes, 13 seconds for the Claimants; and no time for the Tribunal.
For the examination of Dr. Carmelo Rosa, there were 4 minutes, 13 seconds for the Respondent, and 28 minutes and 51 seconds for the Claimants.
In more detail, the examination of Ms. Debra Emerson: Direct examination was 9 minutes, 36 seconds; cross-examination was 35 minutes and 6 seconds; Tribunal questions, 7 minutes, 19 seconds.
For Mr. Lloyd Payne, direct examination was 5 minutes and 12 seconds; for cross-examination, 1 hour and 7 minutes and 11 seconds; and the Tribunal 17 minutes and 4 seconds.
For Mr. Michael Goga, the direct examination was 4 minutes, 43 seconds; for cross-examination, 15 minutes and 13 seconds; no questions for the Tribunal.
And for the examination of Dr. Carmelo Rosa,

939

direct examination was 4 minutes 13 seconds; cross-examination, 28 minutes, 51 seconds; and no time for the Tribunal. Bringing us to a total of 3 hours, 11 minutes, and 47 seconds for the Claimants; 2 hours, 42 minutes, and 6 seconds for the Respondent; 1 hour and 6 minutes and 18 seconds for the Tribunal; for a grand total for Day 3 of 7 hours even and 11 seconds.

PRESIDENT VEEDER: Thank you very much.

Let's continue.

MR. LEGUM: Thank you.

BY MR. LEGUM:

Q. Now, Dr. Rosa, I'd like to refer you to Paragraph 10 of your Second Witness Statement. Here you refer to contamination issues, and you list several specific examples; correct?

A. Yes.

Q. I'm not going to go through all of the examples because of the time, but one of these is [redacted].

Do you see where you discuss [redacted]?

A. Yes.

Q. And you state that this product was

940

contaminated with acetate fibers, adhesive glue, cellulose-based materials, fluorocarbons, hairs, metallic fibers, nylon, polyolefins, and protein-based materials; is that correct?

A. That's what the statement says, yes.

Q. And you reference there, R-42, which is the Signet inspection from 2009; correct?

A. Yes.

Q. Now, it was Apotex that discovered this contamination; correct?

A. It was--the inspection--it was discussed during the inspection. If Apotex would have discovered it and presented it to the Agency, I don't think that was particularly the case.

This was during the inspection. This was discussed during the inspection. I don't have the document--the EIR in front of me to assert if Apotex was who found it.

Of course, I would assume that they're the ones who would detect these because the FDA investigators do not find acetate fibers and none of these components. So I would assume that Apotex was

941

the one who identified the nature of the contaminants.

Q. Okay. Let's take a look at R-42, which is in the Joint Core Bundle at Tab 22. And the specific pages I will ask you to turn to are Pages 41-42.

A. 41?

Q. Do you want to take just a moment to take a look through these pages?

A. You said in regard to--is it Page 38, first paragraph, A, of the observations that you're referring to?

Q. I was referring to Page 41 and 42, which discusses the supporting evidence and relevance.

A. I'm on Page 41.

Q. I'm sorry?

A. Yes, I'm on Page 41 on the supporting evidence.

Q. Okay. Did you want to just read through that discussion and then I'll ask you questions about it? Or would you rather me just ask you questions first?

A. Let me just read it, then.

Q. Thanks.

A. Okay.

942

Q. So Apotex discovered this contamination during its quality checks as part of its manufacturing processes; correct?

A. Yes. That was discovered by Apotex.

Q. And Apotex determined that the contamination was in active pharmaceutical ingredients supplied by a third party; correct?

Sir, please take your time, and let me know if you'd like me to repeat the question.

A. No. I heard. It was found on the API.

Q. The contamination was not introduced by Apotex's manufacturing processes; correct?

A. The issue is not who introduced it; the issue is having the controls. So it's not about who introduced the contaminant; it's about having contaminated product.

Q. And as I've noted before, Dr. Rosa, the counsel for the United States can come back and ask you follow-up questions, if need be. What I'd like to do is come back to my question and ask you to answer that, which is, the contamination was not introduced by Apotex's manufacturing processes; correct?

943

11:06:01 A. I do not know. What I see is that the API was found with the contamination. I wasn't in the inspection, so I cannot say. I do not have the Q-note investigations. I don't have that in front of me. So if Apotex introduced it or not in this particular situation, I cannot state that.

Q. Apotex rejected the batch after it was produced with the contaminated container of API after it was introduced; correct?

A. I would hope they did that, yeah.

Q. But they did do that. That's what was found during the inspection; correct?

A. Yes.

Q. But it's this part of the EIR that you relied on in making your Statement about [redacted] being contaminated?

A. Give me one second. I lost the page here.

Q. It was 41-42.

Oh, I'm sorry, the page of your Statement is Page 4, Paragraph 10.

A. Yes. And [redacted] was contaminated. If you see the observations, A) says [redacted]

944

11:07:43 mixed batch was identified to have been contaminated with that number of things. It's on the 483. That's cited on the 483.

Q. And a mixed batch is one that's an intermediate batch; correct? It's not a final batch?

A. I would not know at this point. I don't have a batch record in front of me to know that.

Q. All right. Let's move on to Paragraphs 11 and 12 of your Second Witness Statement.

A. Okay.

Q. Now, you state here that at the March 31, 2010, meeting, Apotex expressed a commitment to work with FDA to recall possibly contaminated product on the U.S. market.

Do you see that?

A. Yes.

Q. And then in the next paragraph, you refer to, "To that end, Apotex committed to voluntarily recalling over 600 batches of 148 different drug products from the U.S. market."

A. Yes, I see the statement.

Q. Now, the recall was in September 2009;

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11:08:59 correct?

A. The recall was after the Signet inspection.

Q. Right. So the recall that you're referring to in Paragraph 12 is not one that was at issue in March 2010. This was a recall that had already been done in September 2009; correct?

A. Yeah. It's a general statement that they would recall any contaminated products. This was in March 2010, but it would include recalls already done, or recalls ongoing. You don't recall in one month or two months. Recall is a long process. So that's perhaps why the statement was made in that meeting of March.

Q. Okay. Now, further on in Paragraph 10, you refer to the classification of the recall as a Class II recall.

Do you see that?

A. Yes.

Q. Now, we've had a bit of discussion about Class I recall and Class II recalls. Can you tell us what a Class I recall is?

A. I would prefer--recalls--there's an Office of

946

11:10:19 Recalls. I would prefer--and those definitions are within that office. The exact definition, my understanding is that a Recall I involves an imminent risk.

Q. So you're not involved in--

A. --in product recalls. That's not my area, so I would not want to guess on the exact definition of what it is or not.

ARBITRATOR ROWLEY: Can we just correct the record where Mr. Legum referred to Paragraph 10 and I think he meant Paragraph 12.

MR. LEGUM: Yes, it's definitely Paragraph 12. I'm sorry if I misstated that.

BY MR. LEGUM:

Q. But you are involved in assessing whether a product poses an eminent risk or not an eminent risk as part of your functions, no?

A. That's not my direct responsibility. That's part of the assessment that we do in general terms if the products--if the inspection or the inspectional findings represent any imminent risk.

Now, my office doesn't make that exact

947

11:11:44 determination. If there's information to suggest that there's a need for--there's an imminent risk--and "imminent" meaning that should lead to a Class I recall--FDA has a formal process where that evaluation is done.

Q. And who does that evaluation within FDA?

A. Our medical officers within the FDA. There's a group of medical officers that evaluate health hazards and, you know, any type of health hazard issue within the office.

Q. And if we were to think about it in terms of the--kind of the organizational chart of the FDA, would they be part of the CDER or would they be--

A. They would be part of CDER. I believe the officers are under OND, but don't--it is within CDER.

Q. Okay. So probably in the Office of New Drugs, but we're not going to hold you to that.

A. Right. Thank you.

Q. So if you want to know whether a given product poses an imminent risk to public health, you refer the question to that group of medical doctors?

A. If there's a medical--if there's a need for a

948

11:12:55 medical evaluation, yes, it would be referred to doing an assessment to that office.

Q. And was there a referral to that office before the adoption of the Import Alert for Apotex?

A. No. That's not normal common practice within the FDA to--before issuing an Import Alert, to do a medical evaluation. The Import Alert is--that's not part of a necessary--we don't do a medical evaluation for every Import Alert or even, that I recall, for Import Alerts.

Q. So does whether or not a drug or a cGMP issue poses an imminent risk to public health, does that enter into the analysis of whether to impose an Import Alert?

A. When we're considering imposing an Import Alert on products, several factors come into play. They're not all inclusive. One of them is the risk assessment, the risk--evaluate the risk to patient. And the reason for that is if there's an obvious imminent risk, Import Alert may not be the only thing the AC will need to do. See?

But it's not a condition, a precondition to

949

11:14:17 issue and implement an Import Alert on a company. The severity of the observations that I mentioned, the significance of them, the firm's inability to implement Corrective Actions, sustainable corrective actions, repeated violations. Again, many factors. The nature of the violations come into play.

We do consider if there's any imminent risk, of course. That's why we look at Field Alert Reports. That's why we look at the records that we would have available. If there happens to be an adverse events, all that takes into play, and there's a need for that.

But we would not do that evaluation as a condition to place the firm on an Import Alert. If we have it, if we can do it, fine. But we will not want to hold--we would not [sic] want to prevent bad products, adulterated products, from coming into the U.S. because we don't have a medical evaluation because the statute does not require that a medical evaluation be done before we place a firm under Import Alert.

Q. I'd like to turn now to Paragraph 20 of your Second Witness Statement.

950

11:15:38 A. Paragraph 20. Okay.

Q. You state that CDER considered adding Etobicoke to the Import Alert in early 2009, but you did not make that recommendation for several months pending completion of a drug-shortage analysis and the Signet inspection.

FDA performed a drug-shortage analysis for some of Apotex Etobicoke products in June; correct? June 2009.

A. I don't have that in front of me, but I will assume that your statement is correct.

Q. Well, why don't we take a look at C-502, which is in the Joint Core Bundle at Tab 19.

While that's being passed out, I'll note that it is an e-mail chain that begins with one from Edwin Rivera Martinez to Dr. Rosa of June 19, 2009, subject, "Apotex Shortage Information."

Do you see that on the first page, it begins with an e-mail by Valerie Jensen to Michael Smedley and Catherine Gould of June 18, 2009?

A. Yes.

Q. Now, who is Valerie Jensen?

951

11:18:06 A. Valerie Jensen is the director in the Office of Drug Shortages.
Q. So this is the office that the--
A. Under the OND.
Q. It's under OND. And Catherine Gould, who is she?
A. She works in Office of Compliance under the Office of Drug Integrity--the safety office in ODSIR.
Q. And is her role to interface between Compliance and the Drug Shortage?
A. That's one of the roles. We often make a request for drug-shortage assessment if we need their assistance. At that time, we would seek that assistance through Catherine Gould's office, which is part of our Office of Compliance.
Q. So the ordinary process would be, if you wanted shortage information, you would transmit that to the Drug Shortage program through Ms. Gould?
A. We would--this is--we're in 2013. In 2008-2009, we would have that direct communication or we would go through Catherine's group. So at that time that--there was an open dialogue between the two

952

11:19:30 offices.
After FDASIA came, one of the things that we tried do in 2012 and on is to formalize a little bit more and use Catherine's group to channel these requests. But prior to that, we had open dialogue and communications among both offices.
So if I would make a Drug Shortage request or consult and not hear or need it--Catherine's assistance to just check on it, that's normal process or I would just pick up the phone or shoot an e-mail to see what the status of it was.
Q. If you look on the second page, there's a list of products.
A. Okay.
Q. And there's about [redacted] that are listed here. This was not all of the products that Apotex made at Etobicoke; correct?
A. I cannot respond to that. I don't have a list of all the products that they made. But these were the products that were part of assessment, at least at this time.
Q. Right. If you look at the bottom paragraph

953

11:20:40 on Page 2, it says that "In addition to the list that's set out above, we ran an IMS report on Apotex to see if there were any other products besides those in the list forwarded to us by Compliance."
A. Okay.
Q. So that list that appears there is not all of the products; correct?
A. That's what it appears, yeah.
Q. Now, how is a list of products determined by compliance? It looks like that the e-mail train here was Compliance decided that there's this list of [redacted] products that they want the Drug Shortage program's view on. It sends that to Drug Shortage program.
How does that list of [redacted] products develop?
A. No, that's not the way it actually works. The process is, when an investigator does an inspection, one of the common requests that a investigator makes is, "Can I have a list of the products that you manufacture at your facility?" Some would ask a list of specific products shipped to the U.S.
So that any list that we would have, in that

954

11:22:01 sense, is the list that we provide to Drug Shortage for them to do their assessment.
Q. Well, if you look at the last page of this e-mail, it starts with an e-mail from you--
A. Okay.
Q. --to Mr. Smedley, Mr. Santiago, Mr. Rivera Martinez, dated June 1, 2009, where you say, "Hi, Mike. Here is the requested list of products."
So it seems that in this case, it was you that prepared or at least transmitted the requested list of products.
How did you come up with that list?
A. "Attached is the requested list of products."
I'm assuming, again, that there is a list, a formal list, prepared. I don't list 20 or 100 products. I don't recall ever doing that. That list of products, we get it from the inspection report, from the inspectional team, or from even the group that are responsible for importation. They may have--we may ask, "Can you send us a list of products that have been shipped in the last two or three years?"

955

There's different ways to obtain a list of products. And that's--again, I can't recall exactly where I got the specific list, but I certainly did not create it myself.

Q. All right. If you look on the second page, there's a reference to a specific product called [redacted] tablets.

Do you see that?

A. [redacted]?

Q. Yes.

A. Uh-huh.

Q. And you see Apotex had [redacted] percent of the market?

A. Yes.

Q. Based on this information and the other information contained in this list--and I'm looking at the top e-mail on the first page--Mr. Rivera Martinez said: "Based on this information, we may want to hold off on the Import Alert until after our regulatory meeting with Apotex's management."

So Mr. Rivera Martinez decided that the Import Alert should not be adopted based on this

956

information; correct?

A. No. That's not what he's saying. He is saying to hold off until we have the meeting with Apotex--and that is not uncommon--to see if there's new information that would be provided to the Agency that would have an impact on that decision. And at this point, based on that information, we may hold off on the Import Alert until after our regulatory meeting.

Yes, that's what--that's not uncommon to do with any firm that we--we did it here with Apotex, and we do it with any firm. If there's a meeting coming up that they may be providing additional information. Yeah, and we're talking--yeah, this is normal practice.

Q. And when was the regulatory meeting that Mr. Rivera Martinez is referring to?

A. I believe there was a call or a meeting sometime in early July. There was also a call in August 17. So the term "regulatory meeting," although it gives the impression that it is a face-to-face meeting, that may not necessarily be the case. There

957

might be a T-con where we go over important issues. That can be considered, as well, as a regulatory meeting.

Q. Was there a meeting scheduled at this time?

A. I can't recall. It was several years. But there was a--I know there was a T-con or some sort of communication during the month of July.

Q. Dr. Rosa, do you recall requesting another drug-shortage analysis for Etobicoke before recommending the Import Alert?

A. From the top of my mind, I don't. But when we sent consults or requests to Drug Shortage on Apotex, it's very common for them to look at Apotex and which facility, so--

Q. But you don't recall?

A. I don't recall at this time specifically.

Q. Okay. Let's turn to Paragraph 23 of your Witness Statement. Here you state that you reject Dr. Desai's statement that Apotex had no chance to propose corrective actions before it was placed on Import Alert.

A. Certainly.

958

Q. And the basis for that statement is the call that you had with Apotex on August 17, 2009; is that correct?

A. No. The basis for that statement was the inspection of 2006 with significant GMP violations where FDA trusted their response and accepted their response that they were going to correct the issues. The basis for that statement is in 2008, the inspections conducted in 2008. The basis for that statement was the inspection of 2009. The basis for that statement, of course, as well, would take into consideration the August 17 communication.

Apotex had ample opportunity to correct the issues. Apotex had ample opportunity to implement sustainable corrective actions because this is what the Agency has been dealing with. The firm has been unable to sustain a state of compliance and to make products that are in compliance with cGMPs.

This didn't start yesterday. This started in 2006, 2008, 2009, 2011, 2012, 2013. This is what we are working with.

Q. Can you take a look at the Etobicoke EIR,

959

which you already have on your table. It says R-42.
A. Okay.
Q. Now, in here there is a place where the inspector discusses her evaluation of the corrective actions taken by Apotex that were observed in the previous inspection.
A. Can you refer me exactly to a paragraph? I apologize for that.
Q. Hold on one second, please. Oh, yes. No, this is the wrong one. It's R-26 actually for the Etobicoke inspection.
If you take a look at Page 36.
A. Okay.
Q. You see under "Voluntary Corrections"--
A. Yes.
Q. -- where it says, "I have reviewed and verified the corrective actions for the previous 483 given to the firm. I found no deficiencies with the actions taken."
A. I see the statement. And the question is?
Q. You referred in your answer to Apotex not having implemented corrective actions.

960

A. Uh-huh.
Q. The inspector inspected those corrective actions and found no issues.
A. One of the questions and challenges that we always have when we're looking at reports of our field investigators is that there's no indication in this Report about the details of that verification, is one.
So, when I see "I have reviewed"--we appreciate one of the questions and one of the things that we would want to see at the center is specifics about those Corrective Actions. When you look at corrective actions, you know why we think that the corrective actions were not necessarily corrected because we keep finding the same problems in the other facilities. We keep finding the current violations of GMP.
See, the Agency--in this case what we're seeing is that the Agency is going in there and finding the problem for the company, and the company comes and responds and sends a PQA, Product Quality Assessment Report, from consultant.
We are not looking for consultants to submit

961

a PQA. We're not looking for consultant to submit a Report. We are expecting that a firm can sustain their state of compliance, and that's what we are concerned about.
The statement says it was corrected. That is not uncommon. The problem is then when we go to another facility and see--or when we go to the same facility and see recurring problems, certainly the issues were not corrected. Perhaps the snapshot in time, things that were corrected during the course of the inspection, gave the impression that they had been corrected. But the history has told us that that was not entirely correct.
So there could be several issues here. The information provided, maybe the SOPs were corrected, but can we say that they have corrected their state of compliance, their state of quality? Certainly not, because we have done follow-up inspections. We have done inspections at other facilities under the same quality umbrella, and we're saying we've been finding the same problems today in 2013.
Q. So let's quickly review the chronology.

962

A. Yeah.
Q. In 2006, there is an inspection of Etobicoke, and there's a 483; correct?
A. Yes.
Q. Then Apotex proposes corrective actions in response to that; correct?
A. Right.
Q. And then in response to Apotex's corrective actions, FDA states that the proposed corrective actions appear to address FDA's concerns; correct?
A. That's what the statement says.
Q. And then in 2008, there's an inspection of Etobicoke, and the inspector reviews how Apotex performed in implementing the corrections that it promised and states that there are no issues; correct?
A. In 2008--you're saying that in 2008, of course, there were issues. There were the 483 item issue in Etobicoke facility. There was GMP issues.
See, we shouldn't be focused on--we have an exact repeat violations. We had additional violations in this 2008 inspection at Etobicoke.
Q. Okay. So let me repeat my question. I'll do

963

it a little bit slower.
So in 2008, there was an inspection of Etobicoke.
A. Which is this one; right?
Q. That's right.
The inspector reviews how Apotex performed in implementing the corrections that it had proposed in response to the 2006 483 observations; correct?
A. That's the statement that we read in this Report that we referred to.
Q. That's right. On Page 26 of R-26.
The inspector then concludes that Apotex appeared to have adequately implemented its corrections; correct? That's what we just looked at?
A. This inspection was OAI, Official Action Indicated. A Warning Letter was sent on the 2008 inspection. Even though the statement says, "I have reviewed and verified the corrective actions for the previous 483 and found no deficiencies," even though that statement is there, these issues are significant. The products are adulterated. The GMP violations are serious.

964

So you're focusing on the corrective actions. It's not only about corrective actions. It's not about writing an SOP. It's not only about that.
Q. So the answer to my question is that it's correct that the inspector reviewed the corrective actions from 2006 and found them to be adequate?
A. According to that statement, corrective actions were verified.
Q. So let's move on, then.
A. Okay.
Q. The Form 483 was issued, as you've mentioned, at the conclusion of the Etobicoke inspection; correct?
A. Yes.
Q. The firm provided a response to that Form 483; correct?
A. Another response, yes.
Q. Well, there was one response, wasn't there?
A. No. There was one in 2006. There was one now in 2008.
Q. Okay. So--
A. See, you're trying to disconnect one from the

965

other, and we look at the whole picture. We're seeing recurrent issues during inspections. So...
Q. All right. So in 2009 the firm responds to the Form 483 for Etobicoke; correct?
A. The firm responded, yes.
Q. And then in June 2009, FDA issues a Warning Letter for Etobicoke; correct?
A. Yes, that's correct.
Q. The firm responds to that Warning Letter for Etobicoke; correct?
A. The firm responded to the Warning Letter, yes.
Q. And then there's the inspection of Signet, and a Form 483 is issued on August 14, 2009; correct?
A. Yes.
Q. Now, from the firm's perspective, so far as it knew, it had addressed the issues that were identified in the 2006 Form 483; correct? Because that's what the inspector told them.
A. But it's not about the--see, we're focusing on what the inspector tells them. We're not. It's about, "Do you have the system under control? Can you

966

identify and find the problems that you have in your facility?"
We are focused on the evidence--see, to operate in a sustainable state of compliance, it's not about what an inspector finds; it's about the controls and the systems that you have to show that you're sustainable. When we are operating on the basis of what an inspector is finding, that's why we're having the problem that we're having that come up and are recurrent.
Q. Now, would you agree that in order to propose corrective actions, in order to correct cGMP deviations identified by FDA, a firm has to know what those are.
How do you correct a problem unless you know what the problem is stated to be?
A. Okay. I repeat myself. An inspection of an FDA or any regulatory agency is a snapshot in time. We're there several days. Does that mean those are the only problems that the facility could have, or can that be just a tip of the iceberg?
So, again, FDA should not be the one finding

967

these problems because it leads you to the assessment that the only problem that a firm has is the ones that are being identified by the FDA. And that cannot be further from the truth.

Q. So the starting point for our discussion, Dr. Rosa, was your statement that Apotex had an ample opportunity to propose corrective actions. And I think the chronology that we've reviewed shows that Apotex had, at various points, proposed corrective actions as of August 2009.

A. Let me walk you through it again.

Q. No, please, let's not do that.

PRESIDENT VEEDER: I think we've understood what you're saying. Let's let counsel ask the next question.

THE WITNESS: Okay.

BY MR. LEGUM:

Q. Now, Apotex--you advise that--this is Paragraph 23 of your Witness Statement.

A. Okay.

Q. The investigators were instructed to ask Apotex to call CDER the following business day;

968

correct?

A. Yes.

Q. That was a Friday?

A. Uh-huh.

Q. The next business day was a Monday; correct?

A. I don't have a calendar, but I assume that's correct, yes.

Q. Apotex had a single weekend in August to review the cGMP deviations listed by the inspectors, contact consultants, and write up a Corrective Action Plan would adequately satisfy FDA? That's what--that was the opportunity afforded Apotex?

A. No, that was not--I'm trying to understand. The opportunity for what? Because the violations were found during the course of the inspection, at the end discussed with the firm.

The discussion that we wanted to have with the firm by then--by even during the course of the inspection, the firm should have known the seriousness of the violation. The inspectors were instructed, "Tell them to get in contact with the Center for Drugs because we have some serious concern about these

969

violations."

We are not expecting by Monday to have a Corrective Action Plan. We are not expecting by Monday they fix the house. That was not the objective of that request to ask them to call us.

Q. What was the objective?

A. The objective was to listen to what they had to say in regards to these observations, listen to what they had to say in regards to the product that remained in the market, listen to what they had to say regarding the product that was in distribution in the U.S.

Q. So the purpose of the call was not for them to propose corrective actions?

A. No. It was to discuss with them and let them know that we are concerned with the issues that were uncovered during the course of the inspection. That was the objective of that call, to let them know that the Center for Drugs, the FDA, was concerned with these findings, and if they had thought of any measure that they would be taking to ensure that only product that met the quality standards would remain in the

970

market.

Q. Now, you state that other firms halted distribution, temporarily suspended manufacturing, or slowed production of drug products when faced with this level of FDA concern; correct?

A. Yes. There is other companies that have been referenced during this process that has taken different approaches in regards to violations. But the other thing is that the nature of the violations of some of these companies are different. You have--when you look at the Signet Drive inspection, you can see that a facility is not in control.

When you look at Teva Jerusalem and you referenced the Warning Letter before the break, we cannot conclude that Teva Jerusalem was operating out of control in their manufacturing. The follow-up inspection that you made reference to was NAI. Not one single observation was referenced in that follow-up to the Warning Letter.

Two different scenarios.

Q. We'll come to that in a moment, Dr. Rosa.

A. Okay.

971

Q. But as you've mentioned, the Teva Jerusalem facility was inspected from September 12-16, 2010. Was it your understanding that Teva shut down or stopped production on September 17, 2010?
A. Are you--where are you referring to so I can follow you?
Q. You can take my word for it for the dates. Let's assume that Teva Jerusalem was inspected in September 2010.
A. In '10.
Q. Did it stop or suspend production immediately after that inspection?
A. Teva--as soon as that 483 was issued, got on the phone with the Food and Drug Administration. Teva, as soon as that Warning Letter was issued as well. As soon as that Warning Letter was issued--again, the ongoing discussion because one of the things that Teva wanted to do was stop production. They wanted to shut down that facility. Teva wanted to stop production. The Agency was extremely concerned with them stopping the distribution of product.

972

Q. And did they?
A. The Agency had interaction with them and did not--you know, there was an agreement with Drug Shortages, and they did not--that I can recall, those critical medically necessary products or drugs that were in shortage were not stopped.
I cannot say here if any other specific products were not stopped, but I know that the discussions were held with the Drug Shortage officers, and there was a concern by the product that they were making.
If you look at 483, at the Warning Letter--
Q. Dr. Rosa, my question was whether Teva stopped production.
A. They did stop production. They did stop production.
Q. They did?
A. Yes.
Q. All right. We'll come to that again in a moment.
A. Okay.
Q. Did they stop production immediately after the inspection?

973

A. I don't recall. I don't have the information in front of me, but they did take immediate action after.
Q. Did they stop production immediately after the inspection?
A. I would have to go back to some notes here, but as I recall--as I recall, their corporate quality person called me--and I know this firsthand because it was me who this person called--that their intentions were to stop production, to stop distribution of drugs. That's why you will see a chain of e-mails going back and forth because the Agency was extremely concerned with that possibility.
Q. Now, Sandoz's Boucherville facility, it was inspected in July to August 2011.
A. Yes.
Q. Did that facility shut down or stop production immediately after the inspection?
A. That facility--again, immediately after the inspection, I don't recall, but that facility--one of the immediate things that they communicated to the FDA

974

was that they were going to only make critical drug products. There was discussion--
Q. I'm sorry. But my question, Dr. Rosa, was, did that facility shut down or stop production immediately after the inspection?
A. I can't recall if they immediately, like after the 483 was issued. I can't recall that.
Q. Let's turn to Paragraph 25 of your Witness Statement.
A. Yeah.
Q. Here you say that FDA's Import Alert systems were not configured to flag sudden increases in imports in 2009; correct?
A. That's my understanding, yes.
Q. Do you use these systems as part of your job?
A. Our office has--within ODSIR. That's the CDER Office of Compliance, Import Group is there. So when we're placing or recommending an Import Alert, our Import Alert recommendations go to CDER Import Group, who is the one that looks at--Oasis is what the system is called. And they're the ones that send that Import Alert recommendation to them.

975

Q. But do you use those systems yourself?
A. Well, myself, when I was an ORA investigator, yes, I would use it, but not as a director.
Q. Not in your current seat?
A. That's correct. But we have people within the office that do look at these systems.
Q. You state that there are more than 15 million entry lines of FDA-regulated products that are imported into the U.S.; correct?
A. Yes.
Q. And you referred there to Exhibit R-191.
A. Yes.
Q. And you say that's your understanding?
A. Yes.
Q. Is your understanding based on anything other than R-191?
A. Yes. My understanding is based on 18 years working for the field. My understanding is based on years collecting samples on--import samples. My understanding is based on the information that--the people who are the experts on the system. It's just very easy to verify how many import lines we get a

976

year.
Q. Can you just illuminate us on what an import line is?
A. Okay. An import line is basically an entry for every article that would come in. And I would--that's as much as I would want to explain, because the last time I looked at these were several years ago, the specific importation processes. So I would defer that to the center for drug, the import office, to have to explain that.
Q. Now, in Paragraph 26, you say that FDA furnished Apotex with the EIRs, the Establishment Inspection Reports, for the Etobicoke and Signet inspections.
A. Counsel, which statement? I'm sorry.
Q. I'm sorry. We're still on your Second Witness Statement. Paragraph 26.
A. Okay.
Q. Take your time, please.
A. Yes.
Q. Okay. You say that FDA furnished Apotex with the EIRs for Signet and Etobicoke--for the Signet and

977

Etobicoke inspections; right?
A. Yes.
Q. And you're referring there to the 2008 Etobicoke inspection and the 2009 Signet inspection?
A. I'm referring to the inspection reports that were sent to them. I'm not specifying 2008 or 2009 here on the statement. So they had previous observations. They had the 483s. They had the discussions. They had the information about the deficiencies.
Q. So are you saying that the EIRs for the 2008 and 2009 Signet inspections were included in those transmitted to Apotex?
A. No, I'm not saying that. Usually the EIR, when it's under review for a case, is considered an open case. Usually those reports are not released until that action is taken.
So once the Warning Letter is issued, that EIR is usually released. That's the routine process. So the EIR--and, again, I don't have the specific dates, but the EIR should have been released to them after the issuance of the Warning Letter.

978

Q. You didn't yourself transmit those to Apotex?
A. No. That's not--no. I wouldn't do that. The Compliance officer is who normally transmits that information.
Q. Are you aware that Apotex saw those EIRs for the first time in this arbitration when they were produced by the United States as an exhibit?
A. I am not aware, and, again, it was considered an open case. There was follow-up inspections. So if you look at other firms, other firms would not have received them if it's considered an open case.
So we--after that inspection, another Warning Letter was sent to another Apotex facility. So perhaps that might be the reason why that EIR had not been directly released.
Q. So it may be that FDA did not, in fact, furnish Apotex the EIRs further elaborating the cGMP problems in significant detail at that time?
A. FDA furnished the 2006 EIR, describing a significant amount of problem at the Etobicoke facility. So that statement is correct in that sense.
Q. Okay. Let's stay on Paragraph 26 for just a

moment.
A. Yeah.
Q. You state that FDA told Apotex what was needed, from your perspective, to be removed from the Import Alert; correct?
A. Can you refer me to this--this is discussed in T-con. This is discussed in the meetings.
Q. It's the last sentence of that paragraph.
A. What is needed to demonstrate from our perspective to be removed from the Import Alert, yes.
Q. Well, first, who else's perspective would be relevant to making a decision about whether to remove Apotex from the Import Alert?
A. If the Import Alert was--if the firm was added, the products were added on the basis of a GMP inspection, and a GMP inspection--a follow-up GMP inspection is conducted, the same office who initiated that recommendation is the office responsible for, again, writing another recommendation so they can be removed. So in this case it would be our office.
Q. Now, let's turn to Paragraph 27.
A. Okay.

Q. You state that you told FDA--you state that FDA told Apotex in the September 3, 2009, meeting, that it could have submitted testimony to the District where the shipments were held if Apotex wanted to challenge the Detention Without Physical Examination; correct? That's what you say there.
A. No, I'm not saying--I didn't say what you just said. If Apotex has been unsatisfied with the finding, it could have challenged them through mechanisms available. Apotex choose not to do so.
If they had challenged the Detention, it could have been submitted as much as in the September meeting, and FDA stated as much in a September meeting with them.
So I'm not saying that. Your statement is not entirely accurate in terms of--because at the time of these meetings--at the time of these meetings, Apotex was not challenging the Import Alert. At no point in this process--August, September, or even during the inspection, after the issuing of the Import Alert, during that period of time--they were not challenging that Import Alert.

Q. Well, let's take a look at the minutes of that meeting and refresh our recollections about that.
That's Exhibit C-386, which is in the Joint Core Bundle at Tab 37.
A. For the record, these are Apotex's meetings. There's no indication that FDA has agreed with these specific meeting minutes; is that correct?
Q. I believe that these were prepared by Apotex and transmitted to FDA, and FDA never expressed any objections to these meeting minutes.
A. Okay. I don't have recollection of that, but I'll--I would have commented on minute meetings, but I'm going to accept that these are Apotex's minutes.
Q. So you would have commented on them if you'd had any difficulties with the description of what happened; is that correct?
A. No. If the minutes were sent to us for comments and for evaluation and make comments on it, if I had to make comments, I would. I would have, yeah.
Q. And you see the first page of this is an e-mail--let's see. Actually, this is transmitted from

Lance Lovelock to Jeremy Desai. So there may be another e-mail that transmits this on to you, but I don't have that. So I can't say that's the case.
These are the only minutes of meetings that have been produced.
No, that's not right?
I'm corrected. There apparently are other minutes as well.
So the second paragraph here begins, "Apotex opened the meeting by asking for clarification on what the Import Alert meant in terms of product entering the United States. FDA clarified that this meant that all shipments would be held at the border. Appeal could be made to the district in which the shipments were being held to have them released on a case-by-case basis, but that this would required dating"--which I think should be "data"--"showing that the issues resulting in the Import Alert had been addressed."
Is that consistent with what your recollection is of that conversation?
A. Again, I can't recall exactly what was said

983

word by word in that meeting. Appeal could be made--it doesn't say who said that an appeal could be made. I did not say that statement.

Q. Did Mr. Rivera make that statement, Rivera Martinez?

A. I cannot say. I cannot say.

Q. Now, if you look at the last paragraph, which is on the second page, it says, "Apotex asked about what would need to occur for the Import Alert to be lifted. FDA responded that the issues identified in the reports issued would need to be corrected and that the corrections would need to be verified a re-inspection by FDA."

A. That would be a common statement that we would make if a firm was placed on an Import Alert.

Q. So if a firm is placed on an Import Alert as a result of the cGMP inspection, the only way to take the firm off the Import Alert is by doing a re-inspection?

A. That's the current policy that we have in place, at least since I've been at the center, that if an Import Alert is issued on the basis of an

984

inspection, that would be the way to remove from the Import Alert.

Does that mean that that's an absolute? It's not a regulation that that has to be that way, but that's the common practice. Specifically, when you are dealing with a firm that has so many systemic GMP problems, a re-inspection will be needed.

Q. Let's go back to the first page where there's this reference to the statement, "Appeal could be made to the district in which the shipments were being held to have them released on a case-by-case basis, but this would require data showing that the issues resulting in the Import Alert had been addressed."

The data that would show that the issues raised by an Import Alert had been addressed would be through a re-inspection; right?

A. That would be--that would be part of the data. That would be part of the data that could be--again--yeah, that might be part. Information of a re-inspection. If the company has specific information to show that the violations were, indeed, not appropriate, not correct violation, that may be

985

data that they will submit. But an appeal could be made to the district in which the shipments--yeah, they would have to submit it through the process of the office who is actually detaining.

Q. And that would be on a case-by-case basis; correct? It wouldn't be--you couldn't go to the district and say, "District, you should lift the Import Alert"?

A. Who wouldn't say that? I don't understand the question.

Q. Okay. So there's a reference here to an appeal that can be made to the district in which the shipments are being held.

A. Uh-huh.

Q. That appeal could concern just the shipments that were in front of the district; correct?

A. That appears to be correct, but I would defer there to the specific district or the Division of Import, who manages the--the Division of Import Operations is the one responsible for managing the imports with the district offices.

Q. But if CDER has recommended an Import Alert

986

and one has been adopted, the district can't decide that the Import Alert should be lifted by itself?

A. Typically what would happen, if information is submitted at a district office to lift an Import Alert and that information was on the basis--that Import Alert was on the basis of an inspection, the district office would contact the CDER, and--the center, and the center would comment on the information.

Be reminded that when we're dealing with Import Alerts, the issue goes to the center because the center is the district office in that sense for the international firms.

We are--inspection reports or actions are not necessarily initiated through a formal recommendation, as would happen during a domestic inspection, because a domestic has 19 district offices with their compliance branches.

For the international arena firms, the center is who serves that district office. So we're the ones that would handle the review of the inspection reports and issuing--initiating any type of action.

987

12:02:50 Q. So the district wouldn't be able to lift the Import Alert by itself?
A. They--nothing in the FDA happens by itself. Nothing in the FDA. Nobody makes a decision on its own. There's just so many layers of review. So a district office would not, on its own, take on that action. They would consult with the center; they would consult with whoever they have to consult to make the right decision. So...
Q. All right. Let's turn to Paragraph 31 of your Second Witness Statement.
A. Of the Second Statement?
Q. The Second Statement, Paragraph 31.
A. Okay.
Q. Here you've got a couple of bullets about relevant circumstances for Sandoz Canada Inc. and Teva Pharmaceuticals Jerusalem.
A. Uh-huh. Yeah.
Q. So let's start with Sandoz. You say that Sandoz Canada's response to the cGMP violations was to temporarily suspend and slow production at the Boucherville facility; correct?

988

12:03:57 A. Among other issues, among other actions, as ceasing production of nonessential products, ceasing and reassigning productions to other facility or discontinuing the production.
The other action they took--it was not only about that decision affecting the U.S. They also--the decision that they--
Q. Hold on one second. So my--two things. First of all, you're saying "ceasing" production; right?
A. Right.
Q. So the record should be corrected to reflect that.
A. Ceasing production of nonessential products.
Q. So, currently, I'm just focusing on what you've said in your Witness Statement. Okay? So the question was, do you say in your Witness Statement that Sandoz Canada's voluntary response to the cGMP violations was to temporarily suspend and slow production at the Boucherville facility? Is that what you say?
A. I'll have to read it again.

989

12:05:01 Was to temporarily suspend and slow production. That was one of the actions.
They also ceased the production of nonessential drugs and worked closely with the Office of Drug Shortages on supplying critical drugs only to the U.S.
And they did this not only for the U.S.; they did this for the other market to the point that it created a concern in Canada because Canada was also affected by this decision.
Q. So I guess the answer to my question is, yes, you did say that?
A. I will say yes. It's not--
Q. All right. So let's talk about this slowdown first. What we're going to do here, Dr. Rosa, is we're going to focus on different things you said in this paragraph. So let's focus on one at a time, and that way I think we'll have a more organized discussion.
So what we're going to focus on now is the suspension and slowing down of production at the Boucherville facility. That did not happen until

990

12:05:57 March 2012; correct?
A. I do not have the exact date as to when that happened.
Q. Well, do you have the approximate date as to when that happened? Your statement is kind of general on this.
A. In my statement, I don't make a reference to a specific date. I would have to look at the records that we used to make the statements when we were reviewing them.
Q. Does March 2012 sound right to you?
A. The same. I can't. I can't, because if I'm inaccurate on the date, then I'll be questioned on my statement because I'm inaccurate on the date.
Q. Okay. The slowdown in production was about four months after the Warning Letter? Does that sound right, to your recollection?
A. Again, I'll have to refer to the documents and the discussions that we had, but I don't have anything in front of me to point out the specific date.
Q. You don't remember?

991

12:06:51 A. I don't recall the exact date.
Q. Okay. Now, were you involved in this decision to--with respect to Sandoz?
A. On which decision?
Q. The decision not to take any further enforcement action, despite the Warning Letter.
A. We considered, as I mentioned in my statements earlier, when we find GMP violations, Import Alert--
Q. Just one moment. My question is just whether you personally--not your office--but whether you personally were involved in the Sandoz case.
A. I would have to see exactly if I reviewed the exact Warning Letter and the details of the case. But I do recall having discussions and looking at and being involved, to the extent--if I sign off on--you know, like, I was one of the reviewers, I would have to say--meaning one of the senior officers reviewing the case, I would have to refer to the record and see if I was.
Q. So the statements that you make in this Witness Statement aren't necessarily based on what you

992

12:07:56 yourself personally knew and did at the time; is that correct?
A. Are you referring to the first bullet?
Q. Yes, that's right. Sandoz.
A. FDA determined, as a result of drug shortage--yeah. I'm talking here on behalf of the FDA.
Q. Now, you state that Sandoz Canada supplied some medically necessary injectable drugs for the U.S. market?
A. Yes.
Q. How do you know that?
A. Because when we sent the consult for drug shortages, Drug Shortage was extremely, extremely concerned for this firm--for affecting the availability of product that manufactured by this facility.
Q. Now, do you remember which product that was?
A. No, I don't remember. I don't recall specifically.
Q. Does phentolamine mesylate injection ring a bell?

993

12:08:56 A. I can't even pronounce that name, so ...
Q. I can't either actually.
All right. Do you know whether, for that particular product, whether Sandoz-Canada was authorized to sell it in the United States at the time of the Warning Letter?
A. I don't recall. I can't. See, I'm not involved on what specific product or not is made. I'm not involved in the decision of what shortages are caused or not. I'm involved in sending the consult, having the discussion in terms of their assessment, and moving forward based on an agency decision.
Q. All right. So if I wanted to know the specifics of what happened with Sandoz Boucherville, you wouldn't be the right person to talk to; I should talk to someone else in your office?
A. It would be Drug Shortage, but maybe Val Jensen or one of the persons of that office who were responsible for doing that drug-shortage analysis.
Q. Okay. Let's turn to Teva, then.
A. Okay.
Q. Now, when a firm receives an

994

12:10:17 out-of-specification test result for a product, that is a concern for FDA?
A. When a firm receives--
Q. --an out-of-specification test result.
A. When they obtain, based on their analysis, if a product fails, yes, that's a concern.
Q. And FDA would be concerned if a firm selectively used test results to test a product into compliance; correct?
A. Yes. And that's why the Warning Letter was issued to Teva on January 31.
Q. And there was--there were also issues with cross-contamination of potentially hazardous compounds at Teva Jerusalem?
A. Can you show me the Warning Letter? I perhaps will confirm or not confirm.
Q. Absolutely. It is C-191, which is in the Joint Core Bundle at 75.
A. Can you repeat the question, Counsel.
Q. Cross-contamination of potentially hazardous compounds was an issue at Teva?
A. Yeah. The concern here was the facility

995

didn't have separate areas. There was not a direct concern because we didn't have any information to suggest that there was, indeed, a cross-contamination issue here. So we were concerned on the basis that the firm didn't have separate areas.

Now, that to say that we had information that there was a cross-contamination issue at this facility that would raise significant concerns, I cannot say that by reading the Warning Letter. It would have been included in that Warning Letter.

Q. Did Apotex at Signet have separate production areas?

A. We're talking about two different issues. We're talking about hazardous compounds here, and we're talking about--you know, if you look at--when we refer to Apotex, if you look at Signet 483 of 2006, that was citing the same--I believe the same citation was cited on that Signet inspection 2006. That didn't even result in a Warning Letter at that case. In this case it made it to a Warning Letter.

Q. There were dissolution problems with Teva drugs as well, and that's a serious issue; correct?

996

A. Can you refer me to the statement on the dissolution--I'm sorry--that you're referring to on Teva?

Q. That's actually in a different exhibit, which I can--I'm happy to show you. But let's come to that in a moment.

Now, Teva selectively used passing results from a different analysis to approve the same lot that had failed for exceeding impurity specifications; correct?

A. Teva had a test result that had not met the specifications, and they did a retest, and they used the retest result instead of--and did not have any reason for invalidating that specific result. And if you see, this item refers to one product, one incident that the FDA found. One.

Q. So one product?

A. Yeah. Your firm did not investigate when it failed to meet the fact on that large impurity then--yes, on that impurity, that was one incident, one product.

Q. Teva had to recall product in September 2012

997

due to over-thick tablets; correct?

A. I don't recall the exact reason, but they did initiate recall. And I don't know which facilities specifically you're referring to.

Q. Let's take a look at C-566.

A. Okay. I have so many papers up here.

PRESIDENT VEEDER: Is it in the Joint Core Bundle.

MR. LEGUM: Oh, I'm sorry. Is it in the Joint Core Bundle? It's not. I'm looking for it.

PRESIDENT VEEDER: Thank you.

BY MR. LEGUM:

Q. If you could take a look at the fourth page of this document.

A. Okay.

Q. So you see in the middle there, there's a reference to--

A. Yes.

Q. --Teva with the manufacturing being Teva in Israel?

A. Yes.

Q. And you see, "Tablet thickness. Some tablets

998

may not meet weight requirements"?

A. Right. You're jumping from one Warning Letter to another facility; right? That's what you're doing?

Q. This is not a Warning Letter; right?

A. This is the Kfar Saba, Israel, versus the Warning Letter incident was related to a different facility.

Q. But this isn't a Warning Letter; it's a recall; correct?

A. I cannot say. I cannot--from looking at this, I would not be able to relate if this recall specifically is related to the Warning Letter facility in Hamerpe Street, Har Hotzvim, Jerusalem. This is in Jerusalem; this is in Kfar Saba, Israel. Two different sites.

Q. Now, FDA had serious manufacturing issues, correct, in the sense that there were multiple reports of serious injury--(overlapping.)

A. FDA?

Q. Excuse me.

A. Oh, I'm sorry.

Q. Me too. I think we're both getting a little tired. We're coming towards the end.

FDA has emphasized the severity of Teva's manufacturing problems, stating that there were multiple reports of serious injury and illness relating to the use of Teva products; correct?

A. Could you refer me to that? Because it seems like you're referring to another Teva facility, not the one on the Warning Letter.

Q. Well, actually, I'm just asking a question at this point. Do you recall FDA noting that there were multiple reports of serious injury and illness related to the use of Teva products?

A. As I recall, there were some Adverse Event Reports from a product manufacturer at a Teva facility in Irvine in the United States. If that's the one you're referring to, that's the only one I would be able to--

Q. Let's take a look at C-452, which is in the Joint Core Bundle at Tab 96. This is a July 23, 2012, letter from FDA to the Ranking Member on the Committee of Oversight and Government Reform in the House of

Representatives.

A. Okay.

Q. If you could look at Page 4, please.

A. Okay.

Q. You see there that it says, "Multiple reports of serious injury and illness related to the use of Teva's propofol injectable emulsion product prompted an inspection in July 2009"?

A. I see the statement.

Q. Now, so you would agree that there were multiple reports of serious injury and illness related to the use of Teva's products; correct?

A. There were multiple reports, according to this statement, of injury and illnesses.

Q. All right. You state in your Witness Statement that Teva Jerusalem volunteered to cease production until resolving the cGMP violations?

A. So we're jumping on to Jerusalem; right?

Q. We are.

A. Okay. Yes. And Teva in Irvine, just for the record, also has been ceasing production. Actually, this product is no longer being manufactured in Teva

Irvine. They ceased production of that product out of that facility.

Q. The inspection of the Jerusalem facility ended in September 2010; correct?

A. According to the Warning Letter, it says September 16, 2010, yes, that's correct.

Q. And the Warning Letter is from January 31, 2011?

A. Yes.

Q. When did Teva volunteer to cease production?

A. Again, the same thing that I mentioned with Sandoz. I don't have a recollection from the top of my head as to when did they decide to cease production.

But the corporate officer, the quality corporate officer, which I will reserve the name, of Teva is known for being very aggressive in taking the right and appropriate actions. She would not--

Q. Hold on. Let's focus on the question. The question was, when did Teva voluntarily cease production? And you don't remember. Was it--

A. I do not remember, but I know that they did

not necessarily wait.

Q. Was it before the Warning Letter?

A. I don't recall. I don't recall, Counsel.

Q. When did you get the telephone call that you referred to in your earlier testimony?

A. It may have been close to the issuance of the Warning Letter. I do not know. I don't have the exact date.

Q. Let's take a look at Exhibit R-181.

A. Yes.

Q. Which is not in the Joint Core Bundle. This is the wrong exhibit. I'm sorry. It should be C-569.

This is an e-mail dated February 23, 2011, from Dr. Rosa to Valerie Jensen, Catherine Gould, and Douglas Campbell, concerning request to verify MN and drug shortage, Teva Israel Jerusalem facility.

Did you write this e-mail?

A. Let me just go through it very quickly. You're referring to the one on Page--

Q. I'm sorry? It's the first e-mail.

A. The first e-mail. Okay.

Okay.

1003

Q. Now, toward the middle you state--first, let's get an answer to my question. Did you write this e-mail?
A. Yes, I did.
Q. Now, towards the middle it states, "At this time OC has no information indicating that the Teva Israel Jerusalem site has stopped or intends to stop production or distribution."
A. Yes.
Q. Now, was this before or after the telephone call that you referred to?
A. This was after the communication. This actually--this e-mail was clarifying what was discussed in a meeting where I informed the office that Teva had informed me that they had intentions of ceasing production at that facility.
So it definitely--the conversation with Teva did happen prior to this e-mail. This was an e-mail where I'm clarifying that they are not, indeed, going to be shutting down because that--when I reported that during earlier discussions, earlier meetings, there was a concern in the office.

1004

So this is--at this time, Office of Compliance has no information indicating that they--that the Teva site has stopped or intends to stop because that had already been discussed, and we had gotten their commitment that they were not going to stop the production of products at that facility, the distribution.
So this e-mail is written after that communication with Teva.
Q. Now, this e-mail concerns 23 lots of different products that Teva was recalling.
A. Yes.
Q. And the e-mail from Ms. Jensen seems to focus on the decision to recall those 23 products; is that correct?
A. Yes. Actually--yes, that's correct. And what's the question?
Q. Well, you answered my question.
A. Oh, I did.
Q. Okay. So try to help us a little bit more with the date of this telephone call that you referred to in your testimony here today. Was it shortly

1005

before this interchange here? Was it months before this interchange that's reflected in this exchange of e-mails? Was it around same time?
A. Again, I do not recall. What I do recall is that at no point have we asked them to initiate a product recall. This--these 23 batches--actually, I believe the number were around 23.
Q. I'm sorry. My question was a little bit different. My question was when was the telephone call?
A. As I mentioned, I know it was before there date, but I don't know the exact date. I think it is relevant to mention that this action was an action that they took, they took voluntarily. They came to us as part of the information that was cited to them and they voluntarily did a retrospective assessment. They were the ones that decided to initiate this product recall.
Q. Now, the recall that Apotex initiated in August and September 2009?
A. Okay.
Q. Did Apotex volunteer to initiate that recall?

1006

A. Yes. Apotex did initiate a recall, and it was a voluntary recall of batches that were in the market. Again, as I mentioned, when you look at the recall of Apotex, you look at the inspections at Apotex, that was certainly out of control in terms of quality. This was a voluntary decision taken based on two observations that were made.
Q. Now, you refer in your Statement to the drug shortage issue at Teva Jerusalem.
A. Yeah. Can you refer me to the Statement? I just want to make sure.
Q. Still the same paragraph, 31.
A. 31. Okay.
Q. Do you want to take a moment to read that?
A. Yes, thank you. Okay.
Q. Now, the medical shortage assessment, that's not something that you did?
A. No.
Q. And was that done for all of the products at Teva Jerusalem, or was that done only for the products involved in the 23 recalled lots?
A. No. The assessment of a drug shortage is

1007

done as part of the review, as part of a--it is part of the evaluation prior to initiating or issuing the Warning Letter. So our review of medically necessary drug products takes place--when I say "our review," the Food and Drug--the Drug Shortage conducts that review prior to FDA initiating an action. Of course, when they see a firm recalling 23 batches, they have some concern about the availability of those products. They would again reassess to make sure. For example, do they really have to recall? Is there true specific information that these batches need to be recalled? Because they are very concerned about the availability of these products.

So that assessment from Drug Shortage could happen--does happen before the action, but in the case where a firm is recalling, they would certainly--my understanding is that they would again reassess and see the impact of such recall. And if a recall is executed or has been initiated by a firm, it's not unusual for Drug Shortages to try to work with the firm, to try to work with compliance if there's a concern in terms of product shortage.

1008

Q. So Dr. Rosa, the only thing that we have in front of us in this arbitration is this e-mail concerning the analysis for the products involved in these 23 lots.

A. Okay.

Q. Can you help us a bit with the earlier drug analysis that you referred to? Can you tell us more about it?

A. What I can tell you is that a drug analysis, in terms of Drug Shortage, is commonly done prior to every action that the Agency has taken. See, I don't document things to go to arbitration. We do things because it's the right thing to do.

Q. Okay. So you don't remember--you're sure that that was done, but you don't remember anything about that earlier drug shortage?

A. Yes, because as part of our normal process to make a consult of drug shortages.

Q. How many drugs are produced at the Teva Jerusalem facility?

A. I would not know. I would not know from the top of my head.

1009

Q. Give me one moment. Okay?

A. Sure. Can I have some water?

Q. We're terribly sorry. We should have given you that from the very beginning.

A. Thank you. I'm just asking because John said I could ask for the water.

MR. LEGUM: Actually, Mr. President, I think that we probably will have a bit more questions for this Witness, and we're at 12:30. We've been going for an hour and a half. This might be a good time to break for lunch.

PRESIDENT: We'll break for lunch for now, and then you will review your position.

MR. LEGUM: Thank you.

PRESIDENT VEEDER: The Witness will not talk to anybody.

THE WITNESS: That's good.

PRESIDENT VEEDER: Let's break now. Let's come back at 1:30.

THE WITNESS: I appreciate that. I'll leave everything here.

PRESIDENT VEEDER: Leave everything there.

1010

You can talk about anything but not about this case.

MR. DALEY: Mr. President, I just wanted to note, this morning I mentioned we would be handing out the chart of the record cites.

PRESIDENT VEEDER: Yes.

MR. DALEY: Mr. Bigge is going to hand it out now.

PRESIDENT VEEDER: Yes. Please hand it out. Thank you very much for that.

(Whereupon, at 12:32 p.m., the hearing was adjourned until 1:30 p.m., the same day.)

AFTERNOON SESSION

PRESIDENT VEEDER: Are the Claimants ready?

MR. LEGUM: We are, indeed.

PRESIDENT VEEDER: Are the Respondents ready?

MR. DALEY: Yes, we are.

PRESIDENT VEEDER: Let's resume.

BY MR. LEGUM:

Q. Very good.

Let's begin with Exhibit C-574, which is in the Joint Core Bundle at Tab 90, that's 9-0.

(Discussion off microphone.)

MR. LEGUM: So then it's 523.

(Discussion off microphone.)

BY MR. LEGUM:

Q. So Dr. Rosa, do you have Exhibit C-523 in front of you? This is an e-mail chain that begins with an e-mail from Elizabeth Johnson dated September 17, 2009, to yourself, and it's entitled "FDA Slides 2."

Dr. Rosa, do you have that in front of you?

A. Yes, I do; sorry. Thank you.

Q. Do you see that the second e-mail on this

13:34:02 chain is an e-mail from yourself dated Wednesday, September 16, 2009, to Elizabeth Johnson?

A. Yes, I see the paragraph.

Q. Now, the third sentence of that e-mail reads "During the recent meeting with Apotex, we informed them that FDA does not intend to serve as their QA/QC unit, nor inspect them into compliance."

Do you see that?

A. Yes.

Q. Now, could you please tell us what this is all about, about FDA not intending to serve as a QA/QC unit or inspecting them into compliance?

A. Okay. That's a statement that sometimes we make in regards to when there's numerous inspections, working with the company, for whatever reason. Sometimes inspecting a firm into compliance can be interpreted as the number of inspections being conducted, telling the firm everything that needs to be corrected, serving almost as their consultant instead of their regulator.

But here you see that there's two components to that sentence. Not--"inspect them into

13:35:29 compliance," but the first component of that sentence says "does not intend to serve as their QA/QC unit," which is relevant to this e-mail because it's not only about inspecting them, but it's about finding everything for them while we're at the facility.

Q. So just so everybody is clear, "QA/QC unit" means Quality Assurance--

A. Quality Assurance and Quality Control unit.

Q. And so for Apotex, you told them that FDA was not going to serve as their Quality Assurance/Quality Control unit, and it wasn't going to inspect them into compliance?

A. At this time I made that statement, unfortunately, that's what we've been doing until now.

Q. And when you say that, it's because there were--

A. I say that because--

Q. Let me finish the question and then you answer it.

A. I'm sorry.

Q. And that's because you have inspected them again? Is that what you're saying? That you're

13:36:31 referring to the re-inspections in January 2011?

A. I'm referring to the entire history. I'm referring to 2006, 2008, 2009, 2011. When we made these statements--in this particular case, at this point it's September 2009, we're--this statement is including the past inspections, including future inspection, we cannot serve as a quality--to future inspections. Today is 2013, and it seems like we're actually serving as a QA/QC unit and inspecting them into compliance.

Q. So this is an email from 2009?

A. Right.

Q. And so your statement in 2009 was that you weren't going to inspect Apotex's into compliance?

A. Yeah. We did not--

Q. And did you inspect Apotex again, the Etobicoke and Signet facilities, between August of 2009 and January 2011? Were there--

A. There's been several inspections--

Q. Was there another inspection between August of 2009 and January of 2011?

A. There were several inspections. If you see,

1015

13:37:51 I'm not referring to Apotex only Signet and Etobicoke. I'm saying Apotex. This includes Richmond Hill. This includes facilities where they have continuing GMP problems.

From 2009--and this would be all inclusive up until today, Signet, Etobicoke, Richmond Hill, whichever facility we're finding problems in, that's what we're referring to.

Q. Let's turn to the other exhibit, which is C-574. And this is in the Joint Bundle at Tab 90.

A. Okay.

Q. So this is an e-mail chain that begins with an e-mail from Valerie Jensen of August 24, 2011, to yourself and Ilisa Bernstein. Who is Ilisa Bernstein?

A. At that time, she was Acting Office of Compliance Director--I believe she was Deputy Director at the time.

Q. Okay. Now, the second e-mail in that chain is an e-mail from you to Ms. Bernstein, Ms. Jensen, and Keith Olin of August 23, 2011. Did you write that e-mail?

A. Yes, I did.

1016

13:39:32 Q. The subject line is "T-con with FDA and Teva."

Now, in the first paragraph, you refer to glass found in the API produced at their Jerusalem site. Do you see that reference?

A. Yes.

Q. So as of August 23, 2011, there was still glass being found in API produced at this Jerusalem site?

A. You're saying as of, there was still glass, like if there were continuing glasses--from what period are you referring to? This is a Field Alert Report. I don't have the Field Alert Report in front of me to see the timeline of the glass being present on the API.

ARBITRATOR ROWLEY: Can we just know what API is, please?

THE WITNESS: I'm sorry. Active Pharmaceutical Ingredient, Your Honor.

BY MR. LEGUM:

Q. And "Active Pharmaceutical Ingredient" is the substance in drugs that makes them work?

1017

13:40:45 A. Yes, it's the--that has a therapeutic effect, yeah.

Q. So at this point in time, August of 2011, there were still open questions about an investigation into glass found in the active pharmaceutical ingredient produced at the Jerusalem site?

A. Yes, that's what the statement says, that there was a Field Alert Report investigation into an API that was produced in Jerusalem.

Q. And this is about a month before the closeout of the Warning Letter to Teva?

A. I am not sure if we're talking about the same facility. You have an API facility here in Jerusalem being referenced, but the Warning Letter closeout, if you look at the Warning Letter, it refers to citations--if you see citations 21CFR211.192, that's the finished goods manufacturing facility. This may be a different Teva facility, not necessarily the one related to the closeout. I can't say that's the case looking at e-mail.

Q. Is there more than one facility of Teva of Jerusalem.

1018

13:42:00 A. I believe there are. I believe there are. I'll have to verify that, but I believe there are multiple Teva facilities in Israel--I know that there are multiple.

Q. All right. Now, if you look at the second paragraph of your e-mail, it says "All we want to know is what they are doing as a corporation to address their quality issues. FDA has been inspecting them into compliance and all we need to see is a true effort to address their global quality problems."

Do you see that statement?

A. Yes, I do.

Q. Now, here you say, "FDA has been inspecting them into compliance."

What does that mean?

A. The same thing that it meant for Apotex, the same thing. Inspections that we--we did an inspection, the follow-up inspection was NAI. So that's basically the comment. They were inspected into compliance. We found some problems within a previous inspection maybe, and they were found in compliant.

Now, this is a general statement. I'm not referring--I can't say to any specific facility that I'm making that statement towards, but "FDA has been inspecting them into compliance," meaning that there are sites that are making drugs that are in shortage or medically necessary, or sites that FDA has had to work with them because of the need of these products. Basically, that's what this statement is being. But there's--what we did with Teva is no different than what we did with Apotex, regardless of that it says we cannot inspect them to compliance. That's what we ended up doing with Teva--with Apotex.

Q. Let's just back up. And explain to me again just what the words mean "not expecting--inspecting a firm into compliance." Could you please do that?

A. Not inspecting into compliance. Again, in the concept of doing multiple inspections and doing more than what the regulator's responsibility is to do, multiple inspections, finding--in the case of Apotex, when I'm referring to multiple--because you can't disconnect the QA/QC part--multiple inspections, finding the problems for them, and being the ones

identifying the problems for them to correct it.

Q. And so for--

A. In the Teva, just to respond to your question, in the Teva--

Q. Actually, I think you have responded. Thank you?

A. Okay. Well, good.

Q. So. In September 2009 you said that FDA was not going serve as Apotex's QA/QC unit was and was not going re-inspect them into compliance--

A. Which we did.

Q. And then for Teva in 2011, you said that FDA was inspecting them into compliance.

A. Yes. That's a statement that I made there. Taken out of context, could certainly be misinterpreted, I could--but again, the issue is FDA--and this is correct for any regulatory authority. If you're looking at Teva, United States, you're looking at Apotex-Canada, Health Canada would do the same thing and it has done the same thing that the United States did with Teva in Irvine if there's critical drugs being manufactured.

We would have to work with them in that sense, and this is what inspecting into compliance. We would do whatever we would have to in this case because there is some deficiencies found in some of the inspections, the need of the product overcomes the--overcomes the issue of availability. We need that product, and we'll have to work with it. And we have to monitor them very closely. That luxury, when you're dealing with domestic facilities--because you could be at that facility, you could go in at any time you want, we had that statute authority.

I cannot go into Apotex at will. I cannot go into Apotex and get on a plane and just go today and, appear and, knock, knock, I'm here, for a foreign firm. Domestic firm, we have that opportunity, and that's, perhaps, if referring to the Irvine facility or any of the Teva facilities in the U.S., that might be why this comment was made.

Q. But were you referring to the Irvine facility or a facility in the U.S.?

A. I cannot--I'm saying in general. Because we even see that there's a comment there referring to

Teva Virginia. There's a multiple, multiple Teva facilities around the world.

Q. So it's really a comment directed to how you were treating Teva as a corporation?

A. It's not about treating Teva alone, but if you see, all we want to know is what they're doing as a--because there were some concerns, and we wanted them to make sure that they were addressing those issues.

We were interested in the Global Corrective Action Plans. We wanted to make sure that their Global Corrective Action Plans were appropriate and addressed these issues which--not in this e-mail, it is not covered in these e-mails, but I will assume that they were addressed.

Q. And you received a Global Corrective Plan from Apotex as well; correct?

A. I did receive, but it was, unfortunately, just that, a Global written Corrective Action Plan. Nothing that was implemented.

Q. You received that in September of 2009?

A. And we're finding the same problems in

2012-2013.

Q. And the Import Alert was imposed in August of 2009; correct?

A. August 28, 2009, for two facilities.

Q. Dr. Rosa, I thank you very much for taking the time to answer all my questions. You've been very patient. On behalf of Apotex, we thank you again for having taken time away from your functions to be with us today. That concludes our questions of you.

A. Thank you for your time as well.

PRESIDENT VEEDER: Thank you very much. There will now be questions, maybe, from the Respondent.

MR. DALEY: Yes, I have a few, and I'd like to, if I could, a very short break just to check my notes and maybe come back?

PRESIDENT VEEDER: Yes. Do what you need. Five minutes.

MR. DALEY: Right now I think I'll start and at some point I think I'll take a break.

REDIRECT EXAMINATION

BY MR. DALEY:

Q. Dr. Rosa, at some point during your cross-examination, you mentioned something about firms being in control of their processes or not being in control of their processes. What do you mean by that?

A. If you look at--there's a document that is a public document of the ICH Q10, International Conference Organization. You'll see that that document describes many of the expectations. If you actually look at the opening remark of that document, it clearly outlines the expectation of international regulators, and you will see that that document includes a statement that that's FDA's current thinking as well.

When we look and talk about a firm--company being in or not in control, a firm that is capable of identifying the issues, a firm that is capable of predicting the issues, a firm that is capable of implementing Corrective Action Plans that can lead them and can lead them to the point where they can show that they can operate in a sustainable state of control.

If you look at the ICH document,

Section 1.5.2, I believe is the citation, it actually talks about the need to establish and maintain a state of control. When we have a firm that identifies problems, corrects them, and is operating at a level where their investigations are appropriate, when they make--when they decide to reject a batch, it's not rejecting a batch because of trial and error. Let me--if it passes, I release it; if I reject it--if it fails, I'll reject it.

That is not operating in a state of control. That is guessing and crossing your fingers that you can have a good test result.

Q. And I think you mentioned that you had reached the conclusion that Etobicoke and Signet, that those facilities were not in a state of control?

A. Yes. I made that statement.

Q. You were asked some questions about--they were sort of asked in general terms about sterile injectables, and you were asked a question about contamination with, I think, fungal material. And you answered and started to explain that you had to weigh the risk of that fungal material getting out on the

public against the public's need for a drug.

Do you recall that?

A. Yes.

Q. Okay. And then counsel asked you a series of other questions about other kinds of contamination, metal, and so on and so forth.

Would that same kind of balancing factor, the risk of not having the drug, need to be applied to all those other kinds of contamination?

A. Yes. We--when we're dealing with contamination, regardless if it's sterile or solid dose, there is a weigh and balance. We have to evaluate the risks. We have to evaluate the nature of the contamination, the amount of the contamination, lots affected by that contamination, the products distributed with that contamination. Was the contamination a microbial contamination? Was it a--were you finding hair? Were you finding fiber? Were you finding that--metals? That goes into play into that assessment. When we look at that, certainly that goes into that analysis.

Q. And does the Drug Shortage side of it go into

13:52:12 the analysis as well?
A. Yes. We share the information about the violations found with Drug Shortages, certainly.
Q. Dr. Rosa, you mentioned on cross-examination and you were asked some questions about Apotex's response to the Etobicoke Warning Letter being under review, and you mentioned something about a CMS system and the case not being closed out.
Could you just describe for the Tribunal what that means?
A. Yes. CMS is our Compliance Management System, and every case, or every--the several hundred reports and inspections that are conducted, we receive those inspection reports at our office. They are entered electronically. They are scanned and they're entered electronically into CMS. Once they're entered into CMS, they are assigned to a compliance officer, and that compliance officer retrieves it from there, that case, once assigned to him, and initiates its review.
In the international--when dealing with international firms, we receive hard

13:53:22 copies--generally, the inspection reports are received hard copies, and we're responsible for scanning them and entering them into CMS.
CMS, when we close CMS, we tend to close CMS and consider it completed basically after everything has been done. CMS and the other database, FACTS system, those databases are closed only, basic--when all the activities related to that inspection have been closed.
So there's a letter that we send. Let's say you have an inspection that is an acceptable inspection, that the firm was found in compliance, the complete review is conducted. There's a letter sent called the FMD 145 letter--the Field Management Directive letter--saying the inspection has been concluded, everything was reviewed, and your firm is deemed to be acceptable. We issue that letter. When that letter is issued and all that paperwork, then is when the compliance officer goes and closes it in CMS. You will see that it would appear as still under review, but the review has been completed a long time ago.

13:54:34 Q. Okay. Thank you. Could you--you were shown a document C-526 during cross-examination. Could you please find that document? It's a November 24, 2009, e-mail from Hidee Molina.
(Discussion off microphone.)
BY MR. DALEY:
Q. In this e-mail, Ms. Molina says that "Based on my review, both protocols appear to be adequate."
MR. LEGUM: Mr. President, the tradition is for redirect examination to be through nonleading questions.
MR. DALEY: I'm just--I'm not asking a leading question yet. I haven't said anything.
PRESIDENT VEEDER: Which was the first time. We're not going intervene, but just remember that a leading question doesn't produce the same valid answer as an unleading question.
MR. DALEY: Yes.
BY MR. DALEY:
Q. Can you please describe what you understood Ms. Molina to be saying when she said that "both protocols appear to be adequate"?

13:56:50 A. Yes. There are two documents that were sent, that the content of the two documents appeared to have the information that would be appropriate in terms of--let me just--give me one minute.
On the Revised Protocol Quality Assessment of Apotex, for example, if my memory serves me well--which I hate to go by my memory, of course--the PQA, one of the uses of that PQA had to do with the products that were in the warehouse in Indianapolis, I believe it was. So what they submitted was what they were going to do in regards to the product that was in that warehouse. They were going to look if there was investigation, if there were any out-of-specification, if there was any quality issues specifically related to those batches that were at that warehouse.
So that Protocol Quality Assessment is a protocol, this is what we're going to be looking at. And Hidee Molina's review said that that information was appropriate.
Q. Could you turn to R-42. It's the inspection--Establishment Inspection Report for the Signet facility.

1031

13:58:20 A. That's the thick one.
PRESIDENT VEEDER: Just for the sake of transcript later, when you can give the Joint Core Bundle reference--this is Tab 22, I think--could you please do so?
MR. DALEY: Sure.
BY MR. DALEY:
Q. Could you please turn to Page 42. This is the same page you were looking at when counsel asked you questions about before.
A. Yes.
Q. And about halfway through the paragraph, it says--I'm just going to read this to you, and if you could just explain what this means. "The remainder of API batch HY2470 was blocked from future use. However, two other [redacted] batches which were produced using the same lot of API, namely mixed batches HY2815 and HY2816, were ultimately packaged into finished batch numbers HY2910 and HY2912 respectively and were released and distributed to the U.S. market."
What does that mean?

1032

13:59:37 A. That means--that goes to your original question of operating in a state of control. They had problems. There was issues regarding those APIs. And API, as stated by the counsel--a lot was rejected, but batches still made it to the U.S. Meaning batches were actually released under these--with these contaminants.
Q. Dr. Rosa--strike that.
During cross-examination, you mentioned that you received a telephone call from Teva's head of compliance. I think you started to describe that, and then counsel asked you a different question and said we would come back to it, and I'm not sure you ever got back to it. So could you please just describe that phone call.
A. Yes.
Q. And also how the Agency reacted to that.
A. Okay. Can I mention the person's name, or that should--
Q. I think that's okay.
A. I received a call from Fran Zipp, she's the head of quality for Teva. And she was definitely very

1033

14:01:15 concerned with the inspectional findings and was speaking about that Teva will be taking all and any necessary action to remove product from the market that could be affected, and they were ready to cease and stop. She actually ordered--her statement was she ordered that that facility stop producing, stop the distribution.
There was an entire team from corporate that flew to Jerusalem to address the issues to identify--to look at their entire quality system, to look at if any other batches were affected besides the one listed on the 483. That's where the recall comes from. When they did that assessment and looked at other batches, we didn't--we never reviewed those batches. We never had information about those batches. That was done by their own assessment, and they were ready to stop production--to cease production. And she made that statement, "We want to stop production. I'm stopping everything." And that certainly was a concern because of the medical necessary drugs that they manufactured or drugs that they have in--that are in shortage and produced at

1034

14:02:34 that facility.
Q. Why didn't FDA issue an Import Alert for that facility?
A. Again, when we issue an Import Alert, there are several factors that are taken into consideration. And one of them, as I've mentioned, in addition to the seriousness of the issues, to the history of the company, to the ability to do what they say they did, that they were going to do, and the risk that we've talked about, availability of product, drug shortage is a big concern to the Agency to the point that FDA has to report to Congress, to the United States Congress what they're doing to minimize drug shortage situations.
So that's how relevant a drug shortage situation is. They need to know what the Agency is doing in that regard.
Q. You had a similar conversation about the Sandoz Boucherville facility, and I think you mentioned their intention to close that facility--
A. Yes.
Q. --as well. Could you please just describe

that conversation.
A. Right. Also, Sandoz had a similar--
MR. LEGUM: Excuse me, Mr. President, I don't believe that there has been previous testimony about a conversation between this Witness and someone from Sandoz.
PRESIDENT VEEDER: Does this arise out of the cross-examination?
MR. DALEY: There was a--he explained--well, actually, just wait.
BY MR. DALEY:
Q. You explained your understanding that Sandoz intended to shut down that facility. Can you please describe how you reached that understanding and what it was.
A. Right. There was written communication--
PRESIDENT VEEDER: I've got to sort this out. Sorry.
You referred to a conversation, but I don't recall that being raised in cross-examination as a conversation.
MR. DALEY: Sorry. Strike the first

question, and I'll ask it again.
PRESIDENT VEEDER: You need to strike that question and start again.
BY MR. DALEY:
Q. Strike that question.
During cross-examination, you expressed your understanding that Sandoz intended to shut down its Boucherville facility. Can you please describe the basis for that understanding?
A. Yes. The basis--
MR. LEGUM: I'm sorry. Again, Mr. President, I don't remember any kind of statement during cross-examination that the Witness understood that Sandoz would in the future shut down a facility. I don't recall that.
PRESIDENT VEEDER: I don't have access to the transcript. Is there a particular passage you have in mind?
MR. DALEY: Perhaps what I'll do is I'll go to other questions, take a break, and then come back and clean this up.
PRESIDENT VEEDER: Yes, do that.

BY MR. DALEY:
Q. Why didn't FDA put the Sandoz Boucherville facility on an Import Alert?
A. Because--for several reasons. We did not place them on Import Alert--one of them we've discussed today because of the drug shortage situation. That was one of them.
Number 2, Sandoz's corrective and approach--corrective actions and approach were the appropriate corrective actions. Ceasing production, reducing the manufacturing of nonessential drugs was another action. They stopped the manufacturing of drugs, not only for the U.S., but for the rest of the world. That's--those are some of the primary reasons.
The other reason is because the history of that facility gave us no indication that that facility was operating outside or out of control.
When you compare with Apotex, Apotex was clearly operating outside a state of control. Apotex, in the meeting of August 17, we asked them the question, "What do you intend to do?" And one of the statements in that discussion was, "We plan to

continue manufacturing and distributing products."
That was something that was very concerning to the Agency because it gave a clear indication that Apotex wanted to satisfy FDA's application, but not operate in sustainable compliance with GMPs. Because they continued manufacturing product for the rest of the world. They continued releasing products. So those were two different responses and answers to quality issues that were raised in both scenarios.
MR. DALEY: If we could take five minutes, Mr. President.
PRESIDENT VEEDER: Yes, of course. Let's take a five-minute break and come back, let's say, 20 past.
THE WITNESS: Thank you.
PRESIDENT VEEDER: Please don't talk about the case.
THE WITNESS: I won't talk. I don't have any friends.
(Laughter.)
(Brief recess.)
PRESIDENT VEEDER: Before we resume, we just

ought to confirm that we should still be in closed session. Obviously, for the people in the cinema, this is not terribly interesting, looking at a blank screen, but we should, I think, continually review whether we still need to be in closed session.

I assume that that is so, given the questions that have been asked this morning and this afternoon. Can that be confirmed?

MR. DALEY: The questions I'm about to ask I don't think call for product names or anything of that sort, so it probably wouldn't be necessary. I'm not so sure how interesting the last couple minutes are going to be for everyone there.

PRESIDENT VEEDER: For Claimant?

MR. LEGUM: If counsel's view is that the questions are not going to elicit an answer from the Witness that deals with specific products or manufacturing processes, then we can proceed on that basis.

PRESIDENT VEEDER: Well, I think in interest of transparency, we ought to lift the curtain and should now go into open session.

If anything is about to be said or said, we'll obviously go back into closed session.

MR. LEGUM: Would it be useful to just explain for the Witness?

PRESIDENT VEEDER: Yes, it would. Forgive us.

You explain it. It was your idea.

(Laughter.)

MR. LEGUM: Dr. Rosa, as you know, there is some confidential information that is specific to pharmaceutical manufacturing processes, product names, and that sort of thing that you deal with on a daily basis. And we're now going to go into an open session, which means that people in a conference room somewhere else in Washington will be able to hear and see what you--see and hear what you say.

As a result, if you feel like in order to give an answer you need to go into something that you, in your ordinary day-to-day operations, would consider to be confidential, then please let us know so that we can cut the feed.

THE WITNESS: Thank you. And I'll be aware

of that. And I'll say hi to whoever is connecting. Thank you.

(Discussion held off microphone.)

PRESIDENT VEEDER: Thank you very much. Let's return to open session.

SECRETARY TAYLOR: I'm confirming the session is now open.

PRESIDENT VEEDER: Thank you very much. We'll continue.

NONCONFIDENTIAL PORTION

MR. DALEY: Thank you. I wanted to continue with the question to which there was an objection, and the objection is well taken. I've misstated the testimony.

BY MR. DALEY:

Q. So the testimony was concerning Mr. Rosa's statement in his Witness Statement. I'm here on--it's Page 125 of the unedited transcript today. He was asked--I'll just read it out loud into the record.

So currently I'm just--this is the question.

"Q. So currently I'm just focusing on what you've said in your Witness Statement.

"A. Okay.

"Q. So the question was, do you say in your Witness Statement that Sandoz Canada's voluntary response to the cGMP violations was to temporarily suspend and slow production at the Boucherville facility? Is that what you are saying?"

Mr. Rosa goes on to read it again, and then ultimately he answers yes.

1043

14:15:22 And so my question is, what was your basis for understanding that the production was slowed at the Boucherville facility?

A. They submitted the information in writing to us that was going to be the action. They also, during conversations, said that they were going to be eliminating, ceasing production, specifically ceasing, not moving products out that were not--they were not continuing manufacturing products that were not essential products.

In terms of slow production, that is actually one of the documents that they submitted. So that's where the information is coming from, and from conversations and meetings held with the Center for Drugs.

Q. Okay. Another time you were asked questions about Field Alert Reports and you started to add a description of what a Field Alert Report, was and Mr. Legum stopped because it wasn't really the question asked. But I just wanted to give you the opportunity to explain what Field Alert Reports are and why they're important to the Agency. So if you

1044

14:16:30 could just--

A. I really appreciate the question.

Field Alert Report is one of the most important mechanisms that the United States Food and Drug Administration has to obtain information from a firm about quality defects, quality issues. It serves several purposes. It's not only a piece of document that a firm is communicating information through to the Agency. When we receive Field Alert Reports--and that information is used in different ways.

You have a facility, Facility A, manufacturing a drug and finding impurities or finding that there's some problems of assay or dissolution with that particular drug. FDA takes that Field Alert Report and not only looks at the Field Alert--the information from that particular company, it looks at every Field Alert from another company that may be making the same product. So you could have a Company B also experiencing similar problems as Company C.

So it just advises the Agency as early as possible--that's why the regulation provides three days--not to confirm that you know what the

1045

14:17:42 problem is, it's three days from becoming aware of the problem. You have mechanisms to provide updates. There's a follow-up form if--you know, once you have more information in terms of your investigation, and then you can close that report. There's a closeout or a--mechanism as part of the forms that are available.

But the regulatory requirement is for submission within three days because the Agency would make a decision or determination if other similar products made by other competitors are experiencing the same products. From Field Alert Reports, we see decisions made by the Agency to have firms to withdraw applications. We see from Field Alert Reports to have firms to do revisions through their labeling. From Field Alert Reports, we generate an immediate inspection assignment if we have to. There's--Field Alert Reports serve for different, different things and is one of the most important mechanisms that the Food and Drug has.

Otherwise, we would have to wait for a firm to report, if they reported it, in an Annual Report that they were having problems. That might be too

1046

14:18:53 late to become aware of existing problems with a drug that has been approved. Remember, when a drug is approved--if a drug is approved with limited information about the quality of that drug. You do a pilot batch, you do one batch, two batches. Very small information. If you're dealing with generic drugs, you don't even do clinical studies.

But one of the things that the Agency does, when you get a Field Alert Report, if it's from a generic firm, is the innovator making this product and having the same problems?

So there is just so much done. It's an invaluable tool for the Agency. The failure to submit a Field Alert is a very big concern for the Agency. Unfortunately, some companies see it as a piece of paper that just needs to be submitted.

MR. DALEY: Thank you. No further questions.

PRESIDENT VEEDER: Thank you.

The Tribunal has some questions, and the procedure for that is that we ask, each of us, our questions, and then we give a chance to counsel to ask questions arising from our questions and your answers.

1047

14:20:01 So let's start with my colleague on my right. Mr. Rowley will ask you some questions first.
THE WITNESS: Okay.
QUESTIONS FROM THE TRIBUNAL
ARBITRATOR ROWLEY: Dr. Rosa, my questions are going to concern, at the start, just some names of the people who you worked with and what positions they were in. I'm going to ask you--or ask counsel to put in front of you Exhibit C-489, which is that much-maligned organizational chart.
Have you got it?
THE WITNESS: Yes, I have it. It is in front of me.
ARBITRATOR ROWLEY: I'm sorry; it's not dated, so we can't tell precisely what period it applies to. And I am aware that in your Witness Statement you kindly set out your career and when you moved from position to position, but the position names are not always the same as those in this chart. So I'm just going to take you through this chart and ask you a few questions.
THE WITNESS: Okay.

1048

14:21:56 ARBITRATOR ROWLEY: Let's start with yourself. You'll see in this chart you are in the middle bottom blue box which starts with "Brian Belz," and I think you are the fourth person from the bottom there.
THE WITNESS: Yes, that's correct.
ARBITRATOR ROWLEY: And so that's--as I understand it, when you first came in to CDER, you were--what are these? CDER? Are they investigators? Are they compliance officers?
THE WITNESS: Yes. Let me start by saying these charts are, unfortunately, not updated as frequently as they should. If they were part of a presentation, you will see that, in April 2009, the presentation offered by Monica, if this is part of her presentation--
ARBITRATOR ROWLEY: What presentation are you talking about?
THE WITNESS: It says "Overview of the Division of Manufacturing and Product Quality, Case Management and Guidance." I'm not sure if--
ARBITRATOR ROWLEY: Yes, I see it. Yes.

1049

14:22:57 THE WITNESS: Okay. So this chart may be an old chart of the organizational--of the organization. If you look at Anthony Charity there, right above where we're listed--
ARBITRATOR ROWLEY: Well, he's the person in the box above.
THE WITNESS: Yes.
ARBITRATOR ROWLEY: He's described as team leader.
THE WITNESS: Yes. He was acting team leader when I arrived in 2008.
ARBITRATOR ROWLEY: All right. You're going a bit ahead of me. It is all helpful, but--
THE WITNESS: I'm sorry.
ARBITRATOR ROWLEY: --stay with when you got there.
You came in, and were you properly described as being in this bottom box?
THE WITNESS: Yes. When I arrived--
ARBITRATOR ROWLEY: What was your job then?
THE WITNESS: My job was as a compliance officer, and I--it was a lateral transfer. I was

1050

14:23:43 already a compliance officer in San Juan, and it was a lateral transfer.
ARBITRATOR ROWLEY: This is when you moved in here?
THE WITNESS: When I moved in in August 31 on the record, and physically September 18 of 2008.
ARBITRATOR ROWLEY: Perfect. And we're going to follow a rather meteoric rise of your career because I think you then testified earlier you became team leader. Did you replace Mr. Charity?
THE WITNESS: There was not a permanent team leader at the time.
ARBITRATOR ROWLEY: He was acting.
THE WITNESS: He was acting. So there were several announcements to act in that capacity, and I came in as a compliance officer for that group. When the announcement came out as--for acting team leader, I applied for it and my recollection is that I got--I was selected for the acting role in December 30 or 31st of that same year, 2008. And I acted as team leader throughout several months in 2009. When the permanent position was announced, I was selected for

1051

the permanent position in 2009.
ARBITRATOR ROWLEY: And did you report to Edwin Rivera Martinez as Branch Chief at that time?
THE WITNESS: Yes.
ARBITRATOR ROWLEY: And you succeeded him, didn't you?
THE WITNESS: Yes. He retired, and I was acting--I was selected, again, through another announcement to Act Branch Chief, and I was selected to Act Branch Chief. And then when the permanent announcement came out, I was also selected to be the permanent Branch Chief.
ARBITRATOR ROWLEY: And you said Mr. Martinez retired. Where he did he retire to? Is he still alive?
THE WITNESS: Yes, he's alive.
ARBITRATOR ROWLEY: Living where?
THE WITNESS: He's living in Maryland. I don't know where in Maryland. He's working for a pharmaceutical company. He left the Agency. He retired from the Agency but is now working for a pharmaceutical company.

1052

ARBITRATOR ROWLEY: And then I go up, working my way to the top, you're not quite at the top yourself yet but--
THE WITNESS: Sorry.
ARBITRATOR ROWLEY: We then see Rick Friedman, who is Division Director.
THE WITNESS: At the time, Rick Friedman--Edwin Rivera would report to the Division Director, who was Rick Friedman.
ARBITRATOR ROWLEY: And you succeeded him, too, did you?
THE WITNESS: No. There was a reorganization within the Office of Compliance in 2011. Rick Friedman became one of the Associate Directors, and then the branches were converted into Divisions, and there was a detailed--again, as Acting Division Director, when the permanent announcement came out, I became the Division Director. And then--you know, subsequently Alicia Mozzachio and Concepción Cruz became Branch Chiefs reporting to me, the appointed Division Director.
For the Division of International Drug

1053

Quality, at the time of this chart, he was our--our office was called a division. So he was the Division Director, and what we had were different branches. The branch of International Drug Quality--International Compliance, which is the one I'm in, the branch of Domestic Quality, the branch of Policy, and the branch of Good Manufacturing Practice, PAI.
So we had four branches at the time. With the reorganization, those branches each became divisions, and then they would have, subsequently, Branch Chiefs appointed and reporting to the Division Director who was--who were selected.
ARBITRATOR ROWLEY: All right. Well, when you became Division Director of what was formerly a branch, who did you report to?
THE WITNESS: I report as a Division Director to Mr. Steven Lynn, who's the current Director of the Office of Manufacturing and Product Quality.
ARBITRATOR ROWLEY: And was that at the time you reported to Lynn? Have you reported to Lynn since you became Division Director?

1054

THE WITNESS: Yes. In 2012, pretty much. Well--yeah, 2012 is when I--he became--I started reporting to him.
ARBITRATOR ROWLEY: And Joseph Famulare. Is he still with the FDA?
THE WITNESS: No. He also retired, and is also with industry. He's no longer--and this structure is different, if this Honorable Tribunal--if it would make it easier, we could provide a current structure that will facilitate.
ARBITRATOR ROWLEY: I'm not sure the current structure is going to help us all that much--or at least I'm more interested in the structure as it was at the time.
THE WITNESS: Okay. Okay.
ARBITRATOR ROWLEY: Mr. Famulare is working in industry in the United States, is he?
THE WITNESS: I believe so, but I can't confirm that because he travels a lot. We see each other when we're giving conferences in different parts.
ARBITRATOR ROWLEY: And Debra Autor, she was

1055

Office Director at the time. She was part of your chain that you reported up to whilst you were either Branch Chief or Division Director?

THE WITNESS: I would never--I never reported to her directly because I was reporting to the Director above the branch at that time. She was the Office of Compliance Director, so Steve Lynn or Rick Friedman would be reporting to her directly. She is no longer with the Agency either.

ARBITRATOR ROWLEY: When did she leave?

THE WITNESS: I think several months ago. I don't think it's been a year since she retired--she left the Agency. I'm not sure if she retired or not. She did leave the Agency.

ARBITRATOR ROWLEY: Do you know what she does now?

THE WITNESS: She also works for industry.

ARBITRATOR ROWLEY: There's a life after the FDA.

And that's in the United States, isn't it?

THE WITNESS: Yes. In the United States.

ARBITRATOR ROWLEY: And we've heard the name

1056

Janet Woodcock at well. What's her position?

THE WITNESS: She's the current Director of the Center for Drugs, Center for Drug Evaluation and Research. She's been in that position for several years. That's her current position.

ARBITRATOR ROWLEY: She's based here in Washington?

THE WITNESS: Yeah, in White Oak headquarters, meaning White Oak/Silver Spring, Maryland, yeah.

ARBITRATOR ROWLEY: I'm not sure that I really need you to go through some of the things I'm going to ask you about in your Report, but if you could look at your first affidavit--or your First Statement, and I've got some questions that arise out of what you speak of in Paragraphs 59-62.

And by all means, have a look at those paragraphs before I ask you the questions, but I'll point you to any particular thing. But have a look to familiarize yourself with what we're going to be talking about.

THE WITNESS: Okay. Thank you. Yes.

1057

ARBITRATOR ROWLEY: Just before I get there, we were dealing with Mr. Martinez, Mr. Friedman, Mr. Famulare, and Debra Autor.

Do you know whether any of those people were asked to provide Witness Statements for this hearing?

THE WITNESS: I do not know, Your Honor. I do not know.

ARBITRATOR ROWLEY: The Paragraph 59, you'll see in the third line, you begin a sentence at the end of that line, but it concerns--you're saying you were the team leader in charge of reviewing the work of the compliance officers team who went to Signet--or the investigatory team. And you say, "We convened a team meeting to discuss the investigators' observations."

Do you remember who was on the team?

THE WITNESS: Yes. Well, when we say we convene a team meeting to discuss the investigators' observations, as I recall, the team involved the CDER representatives that were part of the inspection. I'm not sure if it also included the ORA investigators, but it's not unusual for the Center to have meetings if people are participating, during inspections.

1058

So there may have been a meeting where the entire team was present. But there was, I think, one or two occasions where we did have a short T-con with the CDER representatives.

ARBITRATOR ROWLEY: And when you have--dealing first with the first team meeting you refer to there, is it the office policy to have a minute of those meetings?

THE WITNESS: Not necessarily. Not necessarily. These are--we have--when we're reviewing a case, there's different--there are so many meetings that go into play when we look at a case or we're evaluating or we're assessing potential actions, but the simple answer is not in every meeting we generate a minute of that meeting.

These--we have core meetings, what we call "core meetings." We have informal meetings between the team. We have T-cons with the inspectors, and not every meeting that we have--

PRESIDENT VEEDER: Let me stop you because I think you've answered the question.

THE WITNESS: I'm sorry.

1059

14:34:57 ARBITRATOR ROWLEY: And so that--it doesn't change whether you're going to consider an Import Alert, for example, or whether you're considering a Warning Letter. Your answer applies to all those meetings.

THE WITNESS: Yes. Yes.

ARBITRATOR ROWLEY: Ms. Zielny, was she part of that meeting?

THE WITNESS: I believe she was, yes.

ARBITRATOR ROWLEY: Anybody else from CDER?

THE WITNESS: Brian Belz, who was the other participant from CDER in the inspection, he must have been part of that meeting as well.

ARBITRATOR ROWLEY: He was the chemist, was he?

THE WITNESS: He was the chemist, yes.

ARBITRATOR ROWLEY: Anybody else?

THE WITNESS: I can't recall the exact people. Usually the compliance officers who are assigned to review the case or who will be assigned to the case will be part of the meeting. The team leader would be part it. The Branch Chief may select to

1060

14:36:01 participate or not in that meeting. I don't recall Edwin being part of that meeting, but it wouldn't be unusual for the Branch Chief to also participate.

ARBITRATOR ROWLEY: And in the next paragraph--two down, 61, on the next page, we--I see you saying "Following discussions with the investigators during the course of the investigation, Ms. Molina began drafting the recommendation memorandum to DIOP." And that recommendation memorandum was regarding the issue of an Import Alert? Am I correct?

THE WITNESS: Yes. That's correct.

ARBITRATOR ROWLEY: And what is your recollection about when you determined that an Import Alert was the appropriate enforcement route to go?

THE WITNESS: An Import Alert--I'm trying to remember, but the Import Alert is one option that we always consider when we're looking at an action, or when we're looking at significant GMP violations. So there's no process for determining, well, we're going to first write the Import Alert or the Warning Letter. There is--that was--at this time, we discussed because

1061

14:37:29 of the seriousness of the issues, the significance of the issues that were uncovered, that an Import Alert would be the most appropriate course of action at this time.

ARBITRATOR ROWLEY: And in Paragraph 62--

THE WITNESS: Yes.

ARBITRATOR ROWLEY: --we see DIOP, or is it DIOP? I don't know what the pronunciation is.

THE WITNESS: Division of Import Operation Programs.

ARBITRATOR ROWLEY: Is the component within the Office of Regulatory Affairs that makes the ultimate decision as to whether to place a firm on Import Alert.

Who at DIOP was concerned with this Import Alert?

THE WITNESS: I don't think--to say that they were concerned or not, I don't think anybody was concerned. This was--in the sense of a standard GMP case where significant violations were found, so we would submit the information, that recommendation to DIOP. They would review it and make sure that we're

1062

14:38:40 following existing process, that they had no concerns about the facilities being placed on Import Alert. So--the responsible person there is Dominic Veneziano and John Verbeten are the people that we normally work with in that office.

ARBITRATOR ROWLEY: What I'm trying to get at, and I think you've answered, but--

THE WITNESS: Okay.

ARBITRATOR ROWLEY: --tell me if I've got it right. I was trying to determine whether there were substantive discussions as to whether this firm should go onto an Import Alert, the discussions with DIOP. And I think you're saying you didn't have substantive discussions with them about whether Apotex should go onto an Import Alert?

THE WITNESS: Right. There wasn't extensive discussions with them. Typically, what the Division of International--of Import Operation appreciates is that, if there's an Import Alert that is being prepared, that we give them a heads-up so they can make sure that they have somebody available to look at that Import Alert.

1063

So there may have been an e-mail in that regards, but I can't recall the specifics of it. But it would not be unusual to send an e-mail. You just pick up the phone, "We're going to be sending an Import Alert recommendation for your review."

But it will go from my office to the CDER import group who were--be responsible for looking at all the facility's products, and they have their own procedure as to what they evaluate. And they send it to the Division of International--of Import Programs.

ARBITRATOR ROWLEY: And so that sort of has to do with my last question on this area.

THE WITNESS: Okay.

ARBITRATOR ROWLEY: Which was what members of senior management, if I may put it that way, were involved in the discussion as to whether to--whether this firm should go on Import Alert at that time? And when I say "members of senior management," I'm thinking about people like Mr. Martinez, Mr. Friedman, Mr. Famulare, Debra Autor.

THE WITNESS: Yes, they were all aware that the firm--we were considering placing them under

1064

Import Alert. They were all aware of that. And that's very common, even today, that any firm that is going to be placed on Import Alert, they are made aware. We have weekly meetings on Thursdays, Fridays, and on Mondays where upcoming Import Alerts, Warning Letters, or communications or any type of action is shared among the management and the senior management.

ARBITRATOR ROWLEY: And are those minuted, those meetings?

THE WITNESS: No. These are Monday--Monday-morning meetings are the ones held by the office directors. The division where I'm at and my director of that office, we hold meetings on Thursdays. We have discussions there, preparing, you know, making sure that any information is made available to the office director--in this case, it would be Steve Lynn--and he would, on Monday morning, go to the office to that meeting and present and have discussions on the upcoming issues.

Currently, there's a database that we use, where--they call it "NTKs," "need to know"--where information of upcoming actions would be documented,

1065

like a summary, a short summary would be shared there. I don't recall if, in 2009, we had an NTK type, but--I can't recall that at this time.

ARBITRATOR ROWLEY: Just a few final questions on training--

THE WITNESS: Okay.

ARBITRATOR ROWLEY: --regarding inspections and enforcement and the various practices of CDER and the FDA.

We've heard testimony and seen documents about practice manuals and regulations and such like. Is there or was there at the time a regular program of training of investigative officers for site visits and of compliance officers for Inspection Report reviews and the like?

THE WITNESS: Yeah. There is a training program that ORA has. They classify them Level I, Level II, Level III investigators. So there is a formal training program that they have for investigators. So that is a training program of specialized inspections. There's a training program where you go to basic drug school. You go to

1066

sterilization courses. You go to specific trainings. You have on-site visits. You're accompanied by a senior inspector while they see you do an inspection. They see you write the 483. So there's a formal training program that the Agency has for investigators.

ARBITRATOR ROWLEY: And in these training programs, did you or any of the team that you were working with at the time of this Import Alert receive any instruction or training as regards the provisions of the NAFTA; that is, the North American Free Trade Agreement?

THE WITNESS: I don't recall any training where specifically we had discussed NAFTA laws. I personally do not recall.

ARBITRATOR ROWLEY: Dr. Rosa, thank you. I think my colleague has some questions.

PRESIDENT VEEDER: Before I hand over to my left-hand colleague, there is one question I'd like to follow up on since it's in front of you.

THE WITNESS: Okay.

PRESIDENT VEEDER: Paragraph 61 of your

second--your First Witness Statement, it's the paragraph that begins "following discussions." If you would go to four lines from the bottom, and there's a sentence that begins, "The Branch Chief then reviewed and cleared the recommendation on August 20, 2009."

Do you see that sentence?

THE WITNESS: Yes, I do, sir.

PRESIDENT VEEDER: Who was the Branch Chief?

THE WITNESS: The Branch Chief at that time? Edwin Rivera.

PRESIDENT VEEDER: Martinez. Okay.

Then we move on. "CDER's Division of Import/Export reviewed and cleared the recommendation that same day."

Again, do you recall the individual or individuals who did that review and cleared the recommendations?

THE WITNESS: That recommendation is sent via CMS, the Compliance Management System, to the Division--the Center for Drugs Division of Import. I do not know who is assigned to the review because they receive it electronically and assign it to an officer

in that division. And so I do not recall who specifically reviewed that.

PRESIDENT VEEDER: Well, let's move to the last sentence. "On August 20, 2009, the DMPQ Division Director cleared the recommendation."

Who was that director?

THE WITNESS: Rick Friedman at that time.

PRESIDENT VEEDER: Thank you very much. Questions now from my left.

THE WITNESS: Okay.

ARBITRATOR CROOK: Dr. Rosa, thank you for your patience with all of us. I have a few questions. Mr. Rowley has taken care of some.

A couple of these relate to this flurry of documents that are in front of you. Could I ask you first to take a look at Lt. Molina's memo, which is C-486 from the bundle that is the Number 14. This is her memo to you of March 20. Highly efficient Claimants are supplying another copy.

I wonder if you would just provide us a little bit of context for one piece of information that is here.

I'm looking at the short paragraph following the box. "We have received [redacted] consumer complaints." Do you see that?

THE WITNESS: Yes, I do.

ARBITRATOR CROOK: Okay. "We have received a [redacted] consumer complaints, [redacted] total Adverse Event Reports since December 2006."

MR. LEGUM: May I just suggest that we go out of--into closed session since we're dealing with a document that deals with specific process issues?

PRESIDENT VEEDER: That should be so. Let's go into closed session.

MR. LEGUM: All right.

SECRETARY TAYLOR: Session is now closed.

CONFIDENTIAL PORTION

ARBITRATOR CROOK: All right. Can you give us a little context, Dr. Rosa? Is that a big number? A small number? Is that a number that catches people's attention for very large producers such as Apotex?

Can you help the Tribunal with some context?

THE WITNESS: Yes. That can represent a

significant amount of complaints, but--and of Adverse Events. But I think what would make them more significant are the reasons or the content of the complaints. If you have complaints that have--that are directly related to quality issues, manufacturing issues, contamination issues, that will put it in a higher level in terms of concern. The same with--the Adverse Event Reports.

ARBITRATOR CROOK: Okay. I think I understand. It's really the content. It's really just more than the raw number.

THE WITNESS: I'm sorry. Than the quantity, yes.

ARBITRATOR CROOK: Okay. Second question relates to another of these documents, and this is C-502 from the Bundle 19. And this is a document that indicates as of June 19--I'm sorry, June 2009, there was apparently some consideration being given to an Import Alert.

Do you have that in front of you?

THE WITNESS: Yes, I do, sir.

ARBITRATOR CROOK: Can you recall or can you

1071

14:50:12 tell us, at what the point did you or members of your staff begin to consider the possibility of an Import Alert?

THE WITNESS: When we received the Etobicoke package, or 483, when you look at the nature of the issues, when you look at 483s, at that point, you will start considering, do we need to consider an Import Alert.

In this case, the Etobicoke 483 was examined, as well as the Signet information. But I--

ARBITRATOR CROOK: Excuse me.

THE WITNESS: I'm sorry.

ARBITRATOR CROOK: Are you able, from your recollection, to relate this in terms of the time? This memo is June 2009. Was this the point at which consideration began to be given, or was it at some earlier point?

THE WITNESS: No. Most likely the consideration began earlier. That's why--I'm sorry; that's why there's discussion about drug shortages. There's discussions about any potential impact on the availability of product.

1072

14:51:18 ARBITRATOR CROOK: Okay. All right. Thank you. We've taken care of that.

Let me just do one last question, and this concerns document C-512, which is in the Bundle Number 26. I think it is probably not one of the many documents in front of you.

I wonder if, perhaps, Respondents would be kind enough to show you the document in the bundle at 26, which I hope is C-512. This is a short e-mail from you to Ms. Molina.

THE WITNESS: Yes.

ARBITRATOR CROOK: Now, the attachments--I see now, this doesn't really--does this memo have any relevance to Apotex? I was struck by the language "we are against the clock," but I see as I read the document, it seems to relate to other firms.

THE WITNESS: Yes. I can explain.

ARBITRATOR CROOK: Okay.

THE WITNESS: Yes. At the time, the purpose of sharing those Import Alert is because we didn't really have a formal template for Import Alert. So these were past recommendations of Import Alerts that

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14:53:14 were used. So some standard language in terms of the--

ARBITRATOR CROOK: Okay.

THE WITNESS: Yeah. That's what it was being used for.

ARBITRATOR CROOK: I understand. Then why did you regard yourself as being under the clock? "We are against the clock."

THE WITNESS: Because the Etobicoke inspection had already occurred in 2008. There was an extensive amount of time passing by. So then we had the recent information of the Signet. So against the clock in the sense we don't want to delay placing a firm that needs to be under Import Alert, we don't want to delay that process because, otherwise, you will be put in a position, if you have to place a firm in Import Alert a year later, why did it take so long to place a firm that you feel that is not in compliance under Import Alert?

So now that--at this time, that we had the information on the Signet facility, that operates on the same quality structure, the same--I'm sorry. I

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14:54:11 talk too fast?

ARBITRATOR ROWLEY: A little bit.

THE WITNESS: I am so sorry.

So at this time, what we did is that--that's what we mean against the clock.

ARBITRATOR CROOK: Thank you. I understand you. It was really--the imperative was to the regulatory situation--

THE WITNESS: Right.

ARBITRATOR CROOK: --with the clock. All right. That's all. Thank you, sir.

THE WITNESS: Thank you.

PRESIDENT VEEDER: I have a few questions as well, which will follow on.

THE WITNESS: Okay.

PRESIDENT VEEDER: The first thing is if we could look at an Exhibit, C-452, you were shown this morning. That's in the common bundle at Tab 96. We were looking this morning at Page--look at Page 6.

THE WITNESS: I'm sorry. You said Page 6?

PRESIDENT VEEDER: Page 6, under Paragraph Number 4. And as I understand it, the FDA is

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14:55:13 responding to a rather official letter from a Member of Congress.
THE WITNESS: I believe that's correct. I wasn't involved in this letter so--
PRESIDENT VEEDER: I just want to ask you to look at the picture on Page 7. Do you see "Trends in Drug Manufacturing Warning Letters and Drug Shortages"?
And it's really the figure for Drug Manufacturing Warning Letters which starts in this graph at 2008 and then jumps a little in 2009, and then a little bit more in 2010. But the figure looks about 30 to slightly over 50 drug manufacturing Warning Letters.
We can't tell exactly from the graph, but historically is that a lot or a little?
THE WITNESS: I think that that's not so uncommon. If you see, this is not only related to the Center for Drugs, so many of these letters are not pertaining to CDER, where I work. Those letters may include letters issued by another center.
PRESIDENT VEEDER: I see. We do have another

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14:56:32 document with some statistics. It is R-86. If you could be given a copy of that, please, Exhibit R-86.
This is explained in the Respondent's Counter-Memorial in Paragraph 63, but we don't need to go there. I just want to ask you to comment on the apparent jump in figures from 2008 to 2009. It seemed we had three Import Alerts there, jumping to 10, which, of course, included Apotex. And then the figure goes higher in 2010, still higher in 2011, and then reaches 20 in 2012.
And if you compare the figures before 2009, they are obviously much lower.
THE WITNESS: Yes.
PRESIDENT VEEDER: Can you confirm broadly these statistics and you can explain why there should be this jump in 2009?
THE WITNESS: Yeah. I can assume that the information is correct.
Now, the jump may not be related only to drug manufacturers. If you recall the time of 2008, 2008 is when the heparin crisis started. So that increased. That significant increase in Import Alerts

1077

14:58:15 may also be related to many firms related to heparin manufacturing that were actually placed under Import Alert.
2011, 2012, a significant amount of firms were placed under Import Alert, factories in China, firms that were supplying drugs that Agency had concern, meaning heparin, in this case.
So that jump--it's not necessarily related to drug pharmaceuticals as we've been relating to during these hearings. But that significant jump might be related to heparin-related facilities that were of concern to the Agency.
PRESIDENT VEEDER: So you--like you say, "you will recall," but I don't, I'm afraid. I've never heard of the heparin crisis. Can you explain what it is and what happened?
THE WITNESS: Yes. In 2008, there was a worldwide crisis involving contamination of heparin coming from China. One--so it was a worldwide crisis. Europe was involved, meaning we had a lot of discussions with Europe and the U.S. in regards to the situation, where deaths were apparently related to the

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14:59:38 use of contaminated heparin with OSCS, oversulfated chondroitin sulfate.
PRESIDENT VEEDER: Were these ingested solid tablets or injections?
THE WITNESS: These were APIs, usually, at that early stage, or at the factory level. That's the information that we concluded, and there's a complete investigation on the Web on that heparin, everything related to heparin that the Agency submitted to GAO. So there's a formal report on heparin.
And at a given time during this, there were factories involved in the manufacturing of crude supply, of crude heparin that were indeed placed on the Import Alert because the Agency concluded that they may have had some relationship with the contamination. So FDA placed them on the Import Alert during that period.
PRESIDENT VEEDER: I think we suggested to you that, in fact, the change was, at least in substantial part, triggered by a change in policy, by a change in the administration of the FDA.
What would you say to that?

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15:00:53 THE WITNESS: I will say that that would be a bit far from what's true because I'm not motivated to do my job or my policy by political--and I mentioned during my Statement that coming from Puerto Rico, there is very few things we know about politics here in the U.S. So I'm not so involved on who is who. I am learning about politics as I see it in the news now, so unfortunately I can't speak to that.

But I--we did not feel that, at least in my responsibility, that anything was motivated by political pressure.

PRESIDENT VEEDER: I take it from your answer that you were not a political appointee.

THE WITNESS: No. I wasn't a political appointee. And I hope I'm never one.

PRESIDENT VEEDER: But if we look at chart that Mr. Rowley showed you, where do the political appointees start, if you start at the top of the page? Are there political appointees on that chart? Or is it higher still?

THE WITNESS: I honestly don't even know when elections are, so I apologize for that.

1080

15:02:03 PRESIDENT VEEDER: Well, take Ms. Woodcock, would she be a political appointee?

THE WITNESS: I don't know. She has been there for like 15 years, I think, or 12 years. She's been around for a while. I hope I'm not mistaken. I know she's been there for many years.

ARBITRATOR CROOK: That answers the question.

THE WITNESS: Sorry. I will just be very honest. I don't know too much about the politics.

PRESIDENT VEEDER: Can we turn to a different topic. If you could be given Exhibit R-43, which is in the Joint Common Bundle at Tab 25.

THE WITNESS: R-43.

PRESIDENT VEEDER: You remember, this is the document you were shown about the conference call on the 17th of August. You're going to be shown the document, so--actually maybe a lot of these bundles should go because there'll be an industrial accident in a moment. We've got reduce the paper.

Now, we've been told this is a call on a Monday after the Friday, which must have been a fairly dramatic meeting for the Apotex staff who met the FDA

1081

15:03:29 representatives. So this call takes place on the afternoon of the Monday, and there are some very senior people on your side, including yourself.

And you express a concern--well, if you start at the bottom of the first page, where this is Mr. Edwin Rivera Martinez inquiring as to whether Apotex intends to continue distributing products.

And there's an answer there from Mr. Desai. "Apotex does intend to continue distributing."

And then you were recorded as saying--this is against CR--"concerned about the decision to continue distributing in the U.S. market considering that Apotex acknowledges significant deficiencies."

Now, how forcibly do you express that point of view? You are clearly a very courteous person. But was this something that you felt was expressed in a way that Apotex understood the significance of what you were saying?

THE WITNESS: I tend to be very clear with my statements. I have--I don't know if this is very true, but I tend to not--with a statement in the U.S., I don't tend to hit around the bushes. When there's a

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15:04:55 concern, I will say as it is, "We are concerned about your continuing your decision to distribute product." I will say it as clear as I can. So I didn't write these minutes, but I assume that--because I did say it in conversations. When I have a concern, I will say it in meetings. I will say it very clearly to the company. I would not say or ignore or not mention if we were not concerned. I would clearly state that. I would not hesitate to make a firm and clear statement.

PRESIDENT VEEDER: Did you mention the words "Import Alert"?

THE WITNESS: We normally--and we do not do this for any company--inform them that we're going to be placing them under Import Alert. That is--I don't recall ever doing that to a firm, that we would be placing them under Import Alert. Unless--like, in this case, the Warning Letter that was issued at Etobicoke did have the warning there that they may be placed on the Import Alert. The Warning Letter of June 25, 2009, does have a statement there.

PRESIDENT VEEDER: One last question. I need to go to your Second Witness Statement to

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15:06:19 Paragraph 77, Page 26. You were shown this again today. Where you say "I strongly disagree with Apotex Inc.'s claim that we treated it less favorably than we treat other firms in similar circumstances."

MR. LEGUM: Mr. President, I'm sorry to interrupt, but the reference that appears in the record is Paragraph 77 of Page 26, which can't be the Second Witness Statement.

PRESIDENT VEEDER: It's the First Witness Statement.

THE WITNESS: Is it the First or Second?

PRESIDENT VEEDER: I beg your pardon. It's the First Witness Statement. Forgive me.

THE WITNESS: Yes. Paragraph 77.

PRESIDENT VEEDER: Paragraph 77. Page 26 of the First Witness Statement.

THE WITNESS: Yes.

PRESIDENT VEEDER: Do you see the first sentence, "I strongly disagree"?

THE WITNESS: Yes.

PRESIDENT VEEDER: If you just jump down about six lines, and then you say, "The extraordinary

1084

15:07:18 time and effort devoted to Apotex Inc. during this time represented a tremendous drain on Agency resources and far exceeded the time we spent on nearly every other drug manufacturing facility during that period."

Can I just ask you how these inspections and the time you spend are funded? Do you charge foreign drug companies for these visits?

THE WITNESS: Not at this time. After the new legislation of FDASIA that came into effect in July of 2012, there's funds, there's Agency--when you submit an application, you have to submit a specific amount of a check or money. I'm not privy to that. I don't know the details.

But at the time of these incidents, FDA inspections, we will not charge any company for any inspection. So every inspection conducted by the Agency was funded by the United States. Every review of application as well. And I think that's very relevant. When we look at 50 applications, 60 or 70 applications, the Agency has to invest months and months and weeks of review to evaluate those

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15:08:42 applications of those drugs that are intended to be manufactured.

And in this case, unfortunately, many of those drugs that were evaluated, where the Agency spent tons of time reviewing them, at the end of the day, when we were getting ready for them, many of them were just, "Oh, we don't want you to cover those. We're not ready for those inspections." The resources that we spent are countless in evaluating Apotex's application, Apotex's inspections, Apotex's state of compliance, the--Apotex's consultant's information.

I will not--there's no hesitation. This is one of the cases where we spent most of--most time reviewing, and I've been involved in injunctions, consent decrees, and prosecutions. This one certainly is one of the top ones in terms of resources consumed for evaluating.

PRESIDENT VEEDER: The Tribunal has no more questions, but are there any questions arising from our questions? We ask Respondent first.

MR. DALEY: No.

PRESIDENT VEEDER: And the Claimants?

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15:09:46 MR. LEGUM: I do have two questions.

PRESIDENT VEEDER: Please go ahead.

RECROSS-EXAMINATION

BY MR. LEGUM:

Q. So I'd like to begin with a question asked by Mr. Crook. He asked you when you began considering an Import Alert with respect to Apotex. And your answer was--you said that you became concerned about issuing an Import Alert when you received the Etobicoke 483 and EIR. I don't have the exact quotation, so I'm paraphrasing.

A. Yeah.

Q. It appears in the record around Page 1061. Could you please take a look at Exhibit C-73, which is in the Joint Core Bundle at Page--at Tab 27. That's going to be handed to you. Don't worry about it.

A. No. That's okay.

Q. They'll bring you a copy.

A. Thank you.

Q. So this is a document that we looked at earlier in the day that is the Sharfstein Report. If you look under "Key Issues," the second sentence says

1087

"DMPQ's suspicion that there may be marketed products was based on a review of exhibits from the inspection which was deemed VAI, Voluntary Action Indicated, by the District."

The Etobicoke inspection was deemed VAI by the District; correct?

A. I'm not sure. My understanding was that there were significant violations. Being VAI or OAI is not unfrequent. It's not uncommon for the--once it gets to the Center, to upgrade an inspection. So--and we have those trends. We have many instances where we get a VAI and it is an OAI. So, yeah.

Q. Understood. My question is do you usually begin considering an Import Alert for an inspection--for a facility that was inspected and noted as VAI, or do you do that after you've considered other information?

A. We--it depends. It depends. We have considered Import Alert even under NAIs. We've issued Warning Letters and we would consider placing a firm on Import Alert even when it's NAI.

Q. My question is really a timing question. So

1088

if you get from the inspectors and the District a file that's recommended to be VAI, do you immediately start thinking about an Import Alert or does that happen at some later point in time?

A. It could happen both ways. We could have a VAI we consider like a high VAI, or--we look at the issues and we could consider placing that--placing a firm under Import Alert with that VAI, is one option that we need to consider. It is not unusual to do that, if needed.

Q. Okay. So my next question concerns an exhibit that the President referred you to. It's R-86. I don't think we have a copy, so if you could bring--if the Respondent could bring that over to you, that would be very helpful.

Now, under questioning from the President, you suggested that this chart might include API, Active Pharmaceutical Ingredients, as well as finished drug products. Do you remember that?

A. Yes.

Q. Now, if you look at the reference there to the left on this chart, the reference is to IA66-40,

1089

GMP issues, human drugs.

A. Uh-huh.

Q. Now, is it your understanding that Import Alert 66-40 addresses only finished human drug products?

A. No, it's not only for finished. You would have APIs under Import Alert 66-40.

Q. So if we looked at the Import Alert 66-40, and it said "Finished Drug Products for Human Use," we should understand that not to be correct?

A. No. You would find finished drug products or a statement saying "all drug products" as well. And that would include APIs.

Q. We'll take a look at the Import Alert.

A. Okay. Great.

Q. I thank you very much for answering my questions.

A. Thank you for your cordiality and your time as well.

PRESIDENT VEEDER: One moment. It looks as though we have a questions.

Is it permissible? What's the question

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about?

MR. DALEY: It arises out of this question.

PRESIDENT VEEDER: Please proceed.

MR. DALEY: Unfortunately, it requires the Witness to look at a document, which is R-25. It is Joint Core Bundle 5. We will just give a chance for everyone to grab it.

FURTHER REDIRECT EXAMINATION

BY MR. DALEY:

Q. Could you describe what that document is, Dr. Rosa?

A. Yes. This document is a document--everyone has it?

Okay. This document is a document that is prepared by the Office of Regulatory Affairs, the inspectors who are conducting the inspection. This is an endorsement document prepared by the investigators with their supervisor, who--and is sent to the Center for Drugs along with the package.

You will see at the bottom of the document that the recommendation by ORA, in this case, the Etobicoke case, was OAI. Recommend recall and many

1091

other things that are listed there. Recommend recall of carbidopa-levodopa due to lack of stability, place product on the Import Alert until firm provides--I'm sorry.

This is the--okay. Below, at the bottom part, you will see the recommended action from the inspector's team or/his supervisor who is responsible for the endorsement. OAI. The recommendation is that we take a regulatory action against--OAI, and then give some suggestions. Recommend recall of carbidopa-levodopa due to lack of stability and place product on the Import Alert until firm provides headquarters with adequate stability data to support current stability, recommend withhold of--do I need to read all of that?

PRESIDENT VEEDER: Let me stop you. We can read it.

THE WITNESS: Okay. I'm sorry.

BY MR. DALEY:

Q. So could you please turn to Page 4 of that document? Just explain what that is.

A. Okay. Yeah. And just--this is related to

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the inspection of Etobicoke. So I just want to mention that there was apparently an earlier document that I was shown that said that it was VAI. So this clearly shows the recommendation that was received by the field for this inspection of December 2008.

And you say to look at what page?

Q. Page 4. My question is, the document you were just shown showed--reflected or said that the District downgraded the recommendation to VAI.

Could you just look at that document and explain whether that's correct or not correct based on that document?

A. No. Based on this, there is no recommendation to downgrade. On the contrary, this document says that the recommendation is for Official Action Indicated, which is what occurred in this case when the Warning Letter was issued and subsequently placed on the Import Alert.

MR. DALEY: Thank you.

PRESIDENT VEEDER: Thank you. Thank you very much. We've come to the end of your testimony.

THE WITNESS: Thank you. I appreciate the

1093

opportunity to be able to speak. Thank you.

PRESIDENT VEEDER: As you may know, you can stay here, but you don't have to stay here.

THE WITNESS: Thank you to all.

(Witness steps down.)

PRESIDENT VEEDER: I suggest we take a break now, we take our mid-afternoon break before we start our next Witness. Let's take 15 minutes. We'll come back at 25 to 4:00.

(Brief recess.)

WILLIAM W. VODRA, RESPONDENT'S WITNESS, CALLED

PRESIDENT VEEDER: Let's resume.

Sir, we'd like you to state your full name and then read out, if you're willing, the words on the Expert Declaration form which is on the desk before you.

THE WITNESS: I'd be happy to do so. My name is William Wilson Vodra.

I solemnly declare upon my honor and conscience that my statement will be in accordance with my sincere belief.

PRESIDENT VEEDER: Thank you very much.

1094

You'll first be questioned from the Respondent.

DIRECT EXAMINATION

BY MR. BIGGE:

Q. Thank you, Mr. Vodra. You are currently retired, is that not?

A. Yes, sir.

Q. What did you do before retirement?

A. I spent about 30 years at the Arnold & Porter law firm here in Washington, D.C., in their food and drug practice area.

Q. And you were--I'm sorry. Go ahead.

A. I worked my way up from associate to senior partner and then retired.

Q. And you said that you were part of the food and drug law practice there. Did you have any experience with cGMP enforcement?

A. In that position? Extensive. Extensive experience. We negotiated--I personally negotiated a number of consent decrees with--on behalf of clients with the FDA involving GMP compliance, including American Red Cross, Telectronics, Mentor Corporation, Abbott Laboratories, and Wyeth Pharmaceuticals.

1095

Q. Now, before you were at Arnold & Porter--you said you worked your way up from associate to senior partner over the course of 30 years--where did you work before that firm?

A. Well, let's start at the beginning. It's easier. I spent two years at a firm out in Ohio after I finished law school, then came to Washington, D.C., where I was first at the--what is now the Drug Enforcement Administration, in their Chief Counsel's office. And we were--our job--my job in particular was to work on regulation of the pharmaceutical industry for manufacture of controlled drugs and so forth. I then was hired by the Food and Drug Administration in their general counsel's office to be the Associate Chief Counsel for drugs and do counseling for the drug center at FDA, where I spent the next years five years before I left and went to Arnold & Porter.

So I had about eight and a half years in government, and then private practice.

Q. Okay. For the benefit of the reporter, I'll just ask you to slow down just a little bit.

1096

A. Okay. Sorry.

Q. While you were at FDA, did you do any particular work on cGMP enforcement or regulations?

A. Yes. I was actually legal scrivener for the revision of the GMP regulations that went on between 1976 and '78. This was a complete overhaul of original regulations that were promulgated after the law was enacted in 1962. And there were a number of deficiencies that had to be addressed and a number of new concepts folded in. So it took about two years of drafting and public comment and--before a final order was issued, and I was fortune enough, I guess is the word to use, to have the opportunity to be the craftsman on the legal language and the legal aspects of that order.

Q. And just to be complete, since we've come at your timeline from two different directions, after FDA, you joined Arnold & Porter--after FDA, you joined Arnold & Porter's FDA practice?

A. Yes.

Q. And what year was that?

A. It was 1979.

1097

PRESIDENT VEEDER: Forgive me for interrupting. We're not hearing any names of drugs.

Do we need to be in closed session?

MR. BIGGE: Yes, I should have made that clear. We do not intend to bring up any names of drugs.

PRESIDENT VEEDER: Let's go into open session.

MR. BIGGE: I apologize.

PRESIDENT VEEDER: Are you aware of what we're doing?

THE WITNESS: Yes, I am. I will avoid naming drugs. If I am pushed someplace to name a drug, I will hold up my hand and say time-out.

(Discussion off the record.)

PRESIDENT VEEDER: In the meantime, please continue.

BY MR. BIGGE:

Q. You have your Report in front of you. Does that reflect your honest opinion, having read documents in this case?

A. Yes.

1098

Q. Do you have any corrections or changes you think are necessary?

A. No.

Q. Now, you've also reviewed the two Expert Reports submitted by Mr. Bradshaw and Mr. Johnson; correct?

A. I did. Yes.

Q. Could you briefly summarize the points that you address in your Report and indicate any areas where you and Mr. Bradshaw and Mr. Johnson continue to disagree?

PRESIDENT VEEDER: Just before you answer, we are in open session.

15:44:18 NONCONFIDENTIAL PORTION

THE WITNESS: Thank you.

I also listened to Mr. Bradshaw's testimony on Tuesday, and I think in the interest of time and not to overwhelm the panel with the intricacies and esoterica of food and drug law--it's a proprietary field we have, we don't want to share too much information--let me identify the four topics I tried to address in my Report and where I think differences still exist.

The first is in the area of risk posed by drugs. As I read the Reply from the Claimants and the Second Report from Mr. Bradshaw and Johnson, the--I thought that the--it went to great lengths to minimize the risk that might be posed by solid-oral dosage form drugs, tablets and capsules, and that suggests that FDA's intervention, regulatory action, was overblown and exaggerated and excessive. And I wanted to emphasize that while I think Mr. Bradshaw agreed with me on Tuesday that the risk posed by a product is not a prerequisite for a GMP action, and that we do agree, I'm not sure we agree that FDA should not take

15:45:44 regulatory action with regard to solid oral dosage forms when there are GMP violations. And I think in this case, there were real risks posed by these products.

The second area that I touched on was the--whether the regulatory regime in toto varies between the United States-based companies, whether United States-owned or foreign-owned, and facilities located outside of the United States.

On Tuesday, I think Mr. Bradshaw said twice--I don't have access to the transcript--but that FDA could produce--while they used different tools, could produce exactly the same results, when they take different regulatory actions, they could do that. And my point is they actually cannot.

They can produce one result that is common, and that is to prevent drugs from being distributed inside the United States. An injunction will prohibit shipment and production. A seizure action will take it out of commerce. And an import detention will prevent it from entering commerce in the United States.

15:46:49 But beyond that, the other consequences of those actions are different. And that's a terribly important point. Different in a way that actually benefits the foreign company offering an adulterated product to the United States compared to a domestic facility producing adulterated products.

An injunction, for example, against a United States-based company has global effect. The injunction cannot say these drugs are GMP noncompliant but they can be exported from the United States. The United States law on exports of drugs requires the drugs basically meet U.S. requirements unless they comply with different laws of the country of importation.

And since everyone agrees, the globe--the developed world certainly has GMP as a common requirement; if a drug is not GMP in the U.S., it can't be exported from the U.S. to another country.

So whereas an import detention operates only on the foreign company shipping drugs to the United States. A company based in the Canada or France or wherever is free to ship its product anywhere else in

15:47:55 the world. FDA cannot interference with that.

So already there is one major difference between an injunction proceeding and an import detention.

Secondly, with regard to a seizure action, when a drug is seized, it's an in rem proceeding. The Government takes custody of the drug. If the Court holds that it is adulterated, the drug can be reconditioned, in theory. In practice, it is very difficult to recondition a drug that was not made in compliance with GMPs to make it in compliance with GMPs. As a result, if it cannot be reconditioned, the drug is destroyed.

When a drug is presented for import to the United States and is refused permission to enter the country, it is turned back to the shipper who can take it back and resell it in some other country if the other country will take it. So, again, there is a difference.

Now, FDA can, in a seizure--could take a seizure action against drugs presented at the border and destroy those drugs, but, for various

1103

reasons--efficiency, most importantly--they turn them back rather than let them in.

So my point is that there is simply not a symmetry and that the--the different tools do not produce exactly the same results. They cannot produce exactly the same results. They will always intrinsically produce results that are harsher for an American-based facility than for a foreign-based facility.

The third topic I discussed was FDA's discretion to select the enforcement tools that it would use in individual cases. And here I'm talking about the law apart from whatever the Treaty obligations of the United States are.

I think that the--Mr. Bradshaw agreed with me on--when he was testifying on Tuesday that FDA has very broad discretion. He thinks that it's limited by--what he used the phrase, "arbitrary and capricious." It can't be--actually, it's arbitrary and capriciously.

I think the legal standard I would say it cannot be used as selective enforcement action; that

1104

is, an action that is pulled out because of improper motivation such as the race or the national origin of the defendant being charged in the matter. And in this case, there has been no discussion about any allegation that I've seen about that.

The fourth thing I talked about in my Report is the process by which the import control works in the United States and the role of the Import Alert in that process. And on Tuesday, I believe that the term that Mr. Bradshaw used was "fruitless" to exercise the rights provided under the statute.

I think that conflates facts and law. I'm going to explain that. As I read the Report from Mr. Bradshaw and Mr. Johnson, both the First and Second Report, they accept the fact that FDA made findings of the significant GMP deficiencies, findings that would be sufficient to support a regulatory action, either by way of action in U.S. courts or by way of import detention. So they started, I believe, with the assumption that FDA had the factual case to make in this situation. And then they say because of that, there really was no effective remedy.

1105

Well, I want to look at the legal side of it. And the legal side provides that if the--the way it works is that if a drug is not manufactured in compliance with GMPs, it is deemed to be adulterated. FDA may refuse admission to the country of a drug that appears to be adulterated. It doesn't have to even prove by a preponderance of the evidence that it's adulterated; the evidence burden is much less because, as you know, the inspection authority is much less overseas.

Thank you. I get nervous. I--it's a congenital problem I've had all my career.

So the way it works is if goods are presented at the border and FDA believes they are adulterated, they issue a Notice of Hold first, what's called Notice Number 1; and then a--notify the shipper and the consignee that they have not released it from the customs at the border. They look at it and then they issue a Notice Number 2, which is a Notice of Opportunity for Hearing. It basically sets forth the reasons why the product is being held and provides the consignee or the owner, either one or both, an

1106

opportunity to come in and challenge that decision.

The regulations provide that there's a hearing before a district officer of the FDA that is someone not connected with CDER or any of other centers, but connected with the Office of Regulatory Affairs, the field force of the FDA. At that hearing--it's an informal hearing. The Rules of Evidence do not apply. Information can be provided by way of facts. It can be done by telephone. It's a very expeditious process. But the Party can present whatever information is appropriate to demonstrate things such as the FDA was factually wrong on GMP compliance or that this product was not affected by the GMP issues that FDA found or that they have remediated the problem and this product was produced after remediation and, therefore, what occurred before no longer pertains to this product.

At the end of that hearing, the Agency makes a decision to either release the goods for--into interstate commerce in the United States, or to refuse admission and turn them back to the consignor. That is the point at which the right of the shipper and the

1107

consignee are determined.

The Import Alert is prior to that time, and it is an internal agency document directed to the field force to tell them to be on the lookout for goods. In particular--you know, this particular thing, so they could decide to exercise these options if they so chose. It is not final agency action. I think we and Apotex agree at that point. Because it's not final agency action, it is not reviewable under the Administrative Procedure Act of the United States. It does not determine the rights of any party. It is, if you will, the complaint in a civil proceeding that results in an opportunity for a hearing, and it's that hearing that adjudicate the rights, not the Import Alert.

And so the focus on the Import Alert as a unique phenomenon is just misplaced. It--and it's--to say, "Well, there was no procedural rights for the Import Alert" is talking about no procedural rights to an instruction that is given by FDA to its own employees. And under the Administrative Procedure Act, there is simply no precedent for that.

1108

So those are the--that's where I think the differences remain.

BY MR. BIGGE:

Q. Thank you. In your Report, you--actually, give me just one minute so that I can get a cite.

In your Report at Page 7, Paragraph 12--are you with me?

A. Yes.

Q. You discuss something, and you have it underlined here, "a closed-loop, self-correcting process." "Could you just briefly explain to the Tribunal what you mean by that term?

A. This is a rephrasing of the GMP system that I've developed over the years to explain it to lay audiences, in particular senior management and boards of corporations who were confronted with allegations of GMP violations to put it into a practical concept.

Essentially what FDA's regulations require is, A, you define the specification or performance goal that you want a particular process to achieve. And at the end of the--let's say making a tablet with five grams of aspirin in it. That's your ultimate

1109

goal. But along the way, you have various steps in the process--mixing the product, compressing the tablets, putting the tablets in the bottles. All those are various steps. You define those steps. You then create Standard Operating Procedures, written procedures of how to accomplish that step. Then you train--hire qualified individuals and train them to perform those steps. You then monitor their performance, document what they're doing, and make sure that it is achieving the results that you intend for it to achieve.

And this is the final and most important part. When it doesn't achieve that result, you go back and find out why it didn't. And there's lots of reasons that have nothing to do with bad behavior. It has to do with power failures or employees being sick the day of work, but you go back and find the root cause, and you take a corrective and preventive action--a corrective action to deal with whatever the impact that deficiency had on the product in the pipeline--before you release it for distribution, and preventive to prevent that problem from occurring

1110

again.

And that becomes the closed loop. So that you are--it's sometimes described as continuous improvement, but essentially it is you know what is going on in your process. And the distinction I draw--which was, I think, Dr. Rosa drew a minute ago about being in control, being in control means you know what's happening in this closed-loop system. It doesn't mean you're always in compliance. You may have products that don't meet specifications. The key is you don't let those products be distributed until you've figured out what went wrong and what the impact of that is.

So being in compliance and being in control are two different concepts. And when a company goes out of control, it can no longer assure that it remains in compliance.

Q. Now, you've reviewed the 483s and EIRs applicable to Apotex for the 2008 and 2009 inspections; correct?

A. Yes.

Q. Can you tell us what you understand from

those reports in terms of what you just discussed, a closed-loop, self-correcting process or a state of control?

A. There were a number of observations. And if you give me a minute, I can look at it. But fundamentally there were various observations about the quality unit releasing goods that had not been--whether there were deviations in the batch that had not been run to the ground in terms of root cause and what the impact was on the batch.

There were failures--

MR. HAY: Can I pose an objection here? This is not part of his Report.

MR. LEGUM: But, moreover, I think we're getting into the manufacturing processes, and so I think we should go into closed session.

PRESIDENT VEEDER: Let's go into closed session immediately.

MR. HAY: Thank you for that.

SECRETARY TAYLOR: Now in closed session.

PRESIDENT VEEDER: Thank you.

CONFIDENTIAL PORTION

MR. HAY: Okay. And I had another objection, which is that there's no discussion in his Report about the 483s and an analysis of them and the particular issues that he now seems to go about into in terms of his Opinion.

PRESIDENT VEEDER: Paragraph 12 onwards is talking of the general theory. It's not an application to this particular case.

And you're taking him, I think, a step further, aren't you?

MR. BIGGE: I am. I believe that Mr. Vodra indicates that he has reviewed the underlying documents when he discusses particular drugs at issue. He obviously is qualified and advises clients on the--

PRESIDENT VEEDER: I'm sure he is, but it's not in his Report. I mean, you can ask him what he means by a "closed-loop, self-correcting process," which is how you began this particular question.

MR. BIGGE: That's fair. I'll withdraw it.

PRESIDENT VEEDER: And I think that's as far as you can do in chief.

MR. BIGGE: That's fine. I'll withdraw the question.

BY MR. BIGGE:

Q. Actually, let's leave the feed off so that we don't have to keep going back and forth.

I am going to ask you about something you do discuss in your Report, which is the significance of the August 17, 2009, teleconference. This is--I'm about to put in front of you Exhibit R-43, which is Joint Bundle 25. R-43.

You discuss this meeting in Paragraph 73 of your Witness Statement. Can you just summarize for the Tribunal what you see in this particular document that is of significance?

I should clarify the record. You discussed this in Paragraphs 72 and 73 in your Report.

A. When I read this document in the chronological sequence, I had to go back and try to recreate a chronological sequence in the exhibits in this case. It struck me this was a turning point in the interactions between the company and FDA in that the company acknowledged that it had GMP deficiencies

more than once in this telephone call that it said it had already determined to withdraw some 640 batches of product from the United States market because they did not comply with GMP. But they intended to continue manufacturing and distributing products into the United States because they believed that they could deliver safe and efficacious product--I'm sorry--and that they hired a consulting group to address their deficiencies.

I think FDA was confronted both with the issue of why were these drugs withdrawn and not others? How do they limit the universe?

FDA, as I say in my Report, is concerned with, if you will, putting metes and bounds or fencing in the scope of a--of products affected by a GMP noncompliance issue. And you sort of have to have a rationale, reasonable basis for saying "these drugs were affected, those drugs were not." Having them made at a different facility would be a logical reason. Having them made on Monday as opposed to Tuesday might not be a logical reason. And there was no clear definition back from the company why they

16:03:25 selected it.
There was a meeting immediately following this meeting within the Agency, for which there is another document, in which the Agency discussed their concerns that the recall was not broad enough. But more importantly, the Agency quite clearly signaled that they were concerned about what the company was doing, and the company indicated it intended to continue going on manufacturing and distributing to the United States market. And that even confronted with what they acknowledged, say, twice in this thing, there are significant deficiencies, they felt they had enough checks in the system that their drugs were good enough. And I think FDA concluded the company simply didn't get it.

Q. I'd like to turn you back to Paragraph 42 of your Report, and I'll give you a moment to read that.

A. Uh-huh.

Q. In the second part of that paragraph you write, "The observations at Signet demonstrated that each of the six of the quality systems FDA evaluates was out of control, that Apotex management did not

16:04:40 have a closed-loop, self-correcting system at Signet and thus Apotex could not reliably assure that Signet products were safe and effective."

And you base this on the 483. So could you explain to the Tribunal in more detail what you mean by that conclusion?

A. The first 483 observation was the Quality unit had failed to fulfill its responsibilities in that components and drug products were not rejected when components and/or drug products failed to conform to the quality they are purported to possess. In other words, the goods did not meet the specifications that had been set up for those products. And yet, nevertheless, they were released into commerce.

The Quality unit is the last gate check within the system under the GMP regulations. And the fact that the Quality unit was not restraining distribution of these products was showing that they did not have control of their system, that goods were still getting out before the adequate checks had been done.

The Second Statement is control procedures

16:05:46 were not established to validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and drug product.

What that means is that you don't know that the procedures you've set up, the methods you've adopted, are sufficiently tightly controlled to guarantee reproducibility batch to batch to batch.

And so those two systems indicate that you didn't have a self--a method for monitoring compliance and correcting the compliance.

And I would just add one more item. It's those two observations that, in the minutes of August 17 meeting, were the ones that company referred to as why they were recalling [redacted] batches from the marketplace.

Q. Now, while you were at Arnold & Porter, you advised pharmaceutical companies in situations similar to this; correct?

A. Yes.

Q. Let me just ask, have you ever advised a company to cease production while it fixes its

16:06:53 problems?

A. Yes.

MR. BIGGE: I don't have any more questions at this time.

PRESIDENT VEEDER: Thank you very much. There will now be questions from the Claimant.

Claimant.

CROSS-EXAMINATION

BY MR. HAY:

Q. Good afternoon, Mr. Vodra. I am John Hay, one of the attorneys for the Claimants in this matter. I'm going to ask you some questions this afternoon. If for any reason you don't understand question or would like me to repeat it, just indicate that and I will be happy to do so. If at any time you need a break, let us know and we will do that as well.

You have your Report in front of you that you've just been referring to?

A. Yes.

Q. Is that a true, correct, and complete statement of all your opinions in this matter?

A. It's complete as to the questions I was asked

by the Government to answer.
Q. Okay. So it's your complete statement of your opinions?
A. Yes.
Q. Thank you.
You are a retired lawyer; correct?
A. Yes.
Q. You retired in 2010?
A. Yes.
Q. You are not a doctor, are you?
A. No.
Q. You haven't had any medical or clinical training, have you?
A. Not formally.
Q. And you're not a scientist, I take it?
A. Not formally.
Q. Okay. Now, you worked at FDA from 1974 through 1979; correct?
A. Yes.
Q. And while you were at FDA, you acted in a role as an attorney; correct?
A. Yes.

Q. You didn't have any operational responsibility, did you?
A. No.
Q. You gave--
A. I was staff. If you mean staff versus line, I was staff, yes.
Q. Okay. Yes, that's exactly what I mean. Your job was to give legal advice; correct?
A. Yes.
Q. You were at the FDA about 30 years ago; correct?
A. Yes. As an employee.
Q. As an employee, correct. That's what I meant; sorry.
A. Have been back many times since then as an adversary, if you will.
Q. After leaving the FDA, you worked for, I believe your testimony was, 30 years at Arnold & Porter; correct?
A. Yes.
Q. In 2010, when you left there, to the present, what--have you been truly retired?

A. No. Part of the reason I retired in 2010 is that I was asked go on Institute of Medicine panel to review--the Institute of Medicine's a branch of the National Academy of Sciences--to work on a project commissioned by the Food and Drug Administration to review the process by which FDA cleared medical devices, Class II medical devices. That was about an 18-month project. And I worked heavily on that project. And then since that time, I've done some consulting. No legal services.
Q. And at FDA, I believe you described what you did as--and I think it's Paragraph 3 of your Report, I was responsible for providing legal advice on (as well as assisting in the drafting of--in the drafting or editing of) proposed and regulations, major policy initiatives, individual regulatory actions, including the approval and withdrawal of new drugs."
Does that accurately summarize what you did at FDA?
A. Yes.
Q. You weren't responsible, as counsel, to approve or review any Warning Letters; correct?

A. At that time we did not call them Warning Letters, and there was no formal review by the Counsel's office.
Q. Okay. You weren't called upon to review, as Counsel, any Import Alerts; correct?
A. Not that I recall. I don't even know if we had the Import Alert policy at that time.
Q. Now, based on your experience in the--dealing with the pharmaceutical industry, are you familiar with Apotex before this arbitration?
A. No personal familiarity. I probably heard the name along with a lot of other generic manufacturers, but I had no familiarity with them.
Q. You didn't know anything about the company?
A. No.
Q. Turning to Paragraph 9 of your Report, and that basically states that, in forming your opinions you reviewed--you had access to and reviewed certain documents; correct?
A. Yes.
Q. Okay. Were there any documents that you didn't have access to that you were aware of? Did you

1123

16:12:44 ask for and was told you can't have?
A. No. I was not asked--I was asked to review the record as it stood at that time. And so I reviewed the documents that had been offered by the Claimants and the Respondents.
Q. Okay. If you look at--I'll take you back a page to Paragraph 8 of your Report. And it starts out by saying, "I've been asked to address the following issues raised in the Apotex Reply."
Do you see that?
A. Yes.
Q. And I take it you were asked by the U.S.?
A. Yes.
Q. Okay. And these are the four issues that you addressed?
A. Yes.
Q. And these are the--with respect to these four issues, that was the extent of your Opinion in this case; correct?
A. Yes.
Q. Let me move ahead to the issue of recalls that you discuss, in part, in your Report. You're

1124

16:14:14 aware that FDA designated the Apotex recall as a Class II recall; correct?
A. Yes.
Q. And before classifying recalls, FDA prepares a Health Hazard Evaluation; correct?
A. Yes.
Q. And do you have any reason to believe that they didn't prepare such an evaluation with respect to the Apotex recall?
A. I'm not aware of--I don't recall seeing it in the documents I reviewed.
Q. Let me show you an exhibit, C-364. I don't believe it's part of the Core Bundle.
Do you recognize Exhibit C-364?
A. Yes.
Q. And this is the breakdown of the various classes of recalls?
A. Yes.
Q. Okay. And so I would like to discuss it with you a little bit. If there's a reasonable probability that the use of a drug will cause a serious adverse health consequence, FDA is required to classify the

1125

16:15:58 recall as a Class I; correct?
A. My problem with your question is the word "required." These are the classifications that FDA adopted for itself. There's no requirement by law that FDA classified a recall at all. They do this for their own purposes.
Q. Okay. So I will rephrase the question, then.
If there's a reasonable probability that the use of a drug will cause a serious adverse health consequence, FDA would classify it as a--the recall as a Class I; correct?
A. Normally, yes.
Q. That was not the case for the Apotex recall; correct?
A. They classified it as Class II.
Q. If there was more than a remote possibility of serious adverse health consequences, FDA would have classified the Apotex recall as a Class I; correct?
A. No. If you look at the definition for Class II, there is two different criterion applicable. One, the one you just read, the remote possibility of a serious health consequence; the other is the use of

1126

16:17:16 or exposure to a violative product may cause temporary or medically reversible adverse health consequences.
So it can cause, if you will, not serious adverse, but temporary or medically reversible adverse consequences, it's still a Class II.
Q. Okay.
A. It's not--it's not a remote-remote. It's rather that the--the risk--the injury likely to occur is medically reversible or transient as opposed to fatal.
Q. Or "serious" is actually the word used here?
A. Serious. Okay.
Q. But my question was slightly different. My question was, if there was more than a remote possibility of a serious adverse health consequence, FDA would have classified it as a Class I; correct?
A. They could have, yes.
Q. That would be their normal practice; correct?
A. I don't know what their normal practice would be. There's a lot of judgment call that goes into this, part of which is when a Class I recall is done, it also triggers off notification of risk to the

1127

16:18:22 public and consumers. And FDA has to balance the risk communication messages against their classification.

Class I recalls are rarely categorized by the FDA. They much more commonly use Class II and Class III.

Q. You mean the FDA doesn't use the Class I classifications? Is that what you just set?

A. They do. But when they do a Class 1 recall, that requires them to consider also public notification. Class 1 recall receives a great deal of publicity in the lay media. So they have to consider, if you will, how many times you cry wolf and what the public can do about it.

A Class 1 recall normally is a situation in which you want to intervene to prevent a, if you will, death or permanent injury, and the public can do something about it.

So the Agency tends to use Class II recalls when they don't have that level of concern for the public safety, immediate concern for public safety.

Q. But if there was more than a remote probability of serious adverse health consequences,

1128

16:19:34 FDA would classify it as a Class 1; correct?

A. Yes. I'm not going to quibble over how you divide being "remote" and "probable." The FDA--it's a judgment call the FDA has to make.

Q. That's what they did in this case; correct?

A. Yes.

Q. And they called it a Class II?

A. Yes.

Q. And that classification would be based on a Health Hazard Evaluation; correct?

A. I would presume so.

My Report in Paragraph 31, where I quote this language, I also quote the other language from the FDA, which uses an example. A drug that's understrength but is not used to treat a life-threatening disease. That's from FDA's own language about the kind of thing that would fall under a Class II.

Q. Which would be a situation that would not--the FDA would consider that there would be a remote probability of serious health consequences; correct?

1129

16:21:01 A. Yes.

Q. Now, at Paragraph 32, you also talk about the fact that FDA has no authority to order the recall of pharmaceutical products?

A. That's correct. No Legal Authority to compel it.

Q. Okay. And the FDA often requests recalls, though; correct?

A. It--the answer--I'll answer this essentially yes.

Q. Okay.

A. And I'd like to explain a little bit further if I can.

Q. Sure.

A. The FDA frequently uses what I'll call a "language of indirection," because they are loath, for a variety of reasons, to be in a position of appearing to coerce a company in doing something that the law does not require it to do. We heard the other day about whether or not asking a company to sign an affidavit was coercion.

FDA, therefore, does not tend to actually use

1130

16:22:05 the words "We hereby request that you recall this product." What they normally do is they ask the company what your intentions are for the product, and the company then responds.

If the Agency really wants the company to do more than that, they will frequently--and I've had this happen on several occasions--say, "We'd like you to do the right thing. We don't think you're doing the right thing yet. Why don't you think about it and give us a call back in 30 minutes."

Then in that period of time, the company decides that it will voluntarily recall, and then the company is able to say publicly--this is another reason why the FDA does it--that the company voluntarily chose to recall the product.

Q. Okay. There's also the statutory or Code of Federal Regulations authority that allows the FDA to request a firm to initiate a recall; correct?

A. Yes.

MR. HAY: Can we show the Witness CLA-564?

(Discussion off microphone.)

MR. BIGGE: Mr. President, while we're on a

break, I just realized that we're still in closed session. I don't know if we are talking about any confidential information. So far it doesn't seem like it.

MR. HAY: It's okay, for the time being, to go out of the closed session, from our perspective.

PRESIDENT VEEDER: We'll go into open session now. Thank you.

SECRETARY TAYLOR: We're now in open session.

NONCONFIDENTIAL PORTION

BY MR. HAY:

Q. Have you had a chance to review CLA-546?

A. Yes.

Q. Is that the copy of the Code of Federal Regulation provision regarding authority for the Food and Drug Administration for requesting a firm to initiate a recall?

A. Yes.

Q. And it is true that, in this case, there is no evidence that the FDA made any effort to request that Apotex initiate a recall?

A. There is nothing that I saw after the August 17 minutes where the FDA posed the question, "What are your intentions with regard to the product?" The Agency never particularized it with a more focused request of "Will you please recall all the remaining products."

Q. And the FDA didn't do that in the August 17 notes that you saw either?

A. That's what I said. I did not see anything in the minutes of that meeting where the FDA used

those words--used words that said, under Section 21 CFR 7.45(a), "We are hereby requesting that you initiate a recall."

Q. They didn't use any words according to--strike that.

My question is, did you see anything in the record where, at any time, FDA made a request or an indication that Apotex should expand its recall or do another recall?

A. No.

Q. You mentioned at Paragraph 33 of your Report third-party testing, and you say that the Agency lacks Legal Authority to impose that requirement; correct?

A. Yes.

Q. Is this a similar situation as you've described in the recall where, even though the FDA has no authority to do that, if they ask a company to do some testing, they will?

A. I have been in situations where they've asked that and the company has done so.

Q. You mentioned here in the last sentence of that paragraph that "In addition, Apotex volunteered

to conduct third-party testing of its products. So no FDA request was necessary"?

A. Yes.

Q. What are you referring to?

A. My recollection--forgive me if I haven't got the details precisely right. It's the Lachman Associate Group. Lachman Consulting presented a Product Quality Assessment Protocol which would be used by Lachman to review the batch records of individual batches and determine that there were no product quality issues with those batches and to have them released.

That may not be testing in the sense of sending it out to the laboratory for testing. I don't recall if the Protocol contained that kind of thing, but that would be a third-party review prior to release of the product.

Again, what you mean by third party--what was meant by third-party testing, I assumed that included third-party review of existing batch records as opposed to simply new laboratory testing. As Dr. Rosa pointed out, you can't test the drug into compliance.

16:27:41 Q. Well, to your knowledge, did FDA ask Apotex to test any of the products that it had sent into the market, either at its warehouse or other facilities?
A. I don't recall.
Q. Now, at 34 you talk about seizing products. Do you see that?
A. Yes.
Q. You say, "FDA did not seize Apotex's products remaining in the U.S. market. Apotex promised voluntarily to stop all further shipments from Apotex Corp.'s Indianapolis, Indiana, warehouse."
Do you see that?
A. Yes.
Q. First of all, I take it from your statement that you would agree that FDA had the power to seize the products in the Indianapolis warehouse?
A. Yes. As far as I know from the record, yes.
Q. And if they want to seize the records at the Indianapolis warehouse, the Party that they would have to bring into Federal court would be Apotex Corp.; correct?
A. No. The seizure is an in rem proceeding.

16:28:58 The warrant for seizure would be listed as a quantity of drugs consisting of, and then a long inventory. The warrant was then served--be served by U.S. Marshal, and FDA would then post a notice in the public domain.
And at that point, any person who had an interest in that quantity of goods could file a notice of claim and intervene in the action. But the action is actually an action in rem against a quantity of product as opposed to a person.
Q. In your view, could Apotex Corp. intervene in that?
A. Yes. As an owner of the goods, yes.
Q. There was some period of time when the drugs were in the Indianapolis warehouse after the Import Alert but before this promise; correct?
A. Yes. I have, since I wrote this record--it--it's not a correction, but I looked at the slides of September 11 meeting by Apotex. They presented the FDA's regulatory meeting on September 11. And in those slides, the first item, I think, is that Apotex informed FDA on the September 11

16:30:07 that they were suspending all distribution of the products from the Indianapolis warehouse.
Q. So that was like a period of two weeks between the Import Alert and that September 11 meeting?
A. Yep.
Q. Okay. And during that time, there's--do you recall seeing any evidence in the record that Apotex tried to dump its product in the Indianapolis warehouse on the public?
A. I see no evidence one way or the other.
Q. As a matter of fact, it's the opposite: Apotex went to FDA and said that they would not sell the product; correct?
A. On September 11, yes. That's the earliest notice I have of it.
Q. The next item you talk about on Paragraph 35 is the Public Health Advisory and Healthcare Provider Advisory, and you said that they're meaningless?
A. Yes. In this context, I believe so.
MR. BIGGE: Objection. I would ask that you read that sentence in full to make the record clear.

16:31:10 BY MR. HAY:
Q. Sure. "The fact that FDA did not issue a Public Health Advisory or a Healthcare Provider Advisory is meaningless."
Those advisories, or at least the Public Health Advisory, usually applies, I think you make the point, to specific drugs.
Is that the way that usually works?
A. Yes.
Q. Okay. Were there any of the Apotex drugs that were subject to a--as an individual drug, subject to Public Health Advisory?
A. I don't recall seeing any. Normally, an advisory would be given out so that a healthcare provider or a patient would have, if you will, the last clear chance to prevent injury. A recall, even down to the retail level, takes time, often months.
And if you've got particulate matter in a bag that's an injectable, for example, or in a bottle, you can see that; and the doctor can, therefore, know not to inject that product. So there's a chance of somebody intervening.

16:32:12 If it's a bottle of tablets, where there's nothing visible on the tablet and it's not unique to that product or whatever, the advisory really does not help the public at all.

Q. In this case, though, you're not aware of any public advisory regarding any of the Apotex products?

A. No.

Q. And the last sentence on Paragraph 36, if you could read that to yourself. And in particular, I'm interested where you reference the possible risk of temporary or medically reversible adverse health consequences from the products.

A. Uh-huh.

Q. Okay. You're using that language from the Class II recall?

A. Yes.

Q. Okay. So, but there was no indication that--there was not a--strike that.

There was no probability of a serious adverse health consequence, though, correct, as defined by the Class II?

A. I will just stick with what the Class II

16:33:48 definition was. We're getting into semantic discussions here, which I don't think are terribly useful to the panel.

MR. HAY: I think if we could cut the feed at this point, because there is a few minutes where I will be talking--

PRESIDENT VEEDER: Let's cut the feed.

SECRETARY TAYLOR: Feed now cut.

PRESIDENT VEEDER: Thank you.

16:34:19 CONFIDENTIAL PORTION

BY MR. HAY:

Q. Okay. In the next few paragraphs, you begin to talk about--you give three examples of drugs that you opine possessed real, not hypothetical, risk to the patients; correct? And the first drug, divalproex, that was part of the recall?

A. Would you repeat the question?

Q. Yes. Yes. That first drug that you referred to, the divalproex?

A. Divalproex.

Q. Right. That was part of the recall; correct?

A. Yes.

Q. Okay. And that drug being part of the recall, it was the FDA's conclusion that there was--the probability of a serious adverse health consequence was remote; correct?

A. I'm not--I'm not aware of any drug-by-drug review that the FDA did on the assessment. The FDA had 640 batches of products. I forget. There were 42 different chemical entities involved. I've never seen a review entity by entity, so I can't tell you they

16:36:03 made a decision about divalproex in particular.

Q. But they classified it as Class II?

A. They classified the entire recall as Class II, yes.

Q. And that was part of the recall?

A. Yes.

Q. Okay. And the same with the tramadol tablets; correct? That was part of the Class II recall?

A. I believe so, yes.

Q. And presumably they did some kind of Health Hazard Evaluation regarding that drug when they put it--when they did the recall?

A. Yes. Can I address that for a little further?

Q. Sure.

A. The issue with this product was an over-thick tablet. You may recall earlier, and I think it was either Teva or the Sandoz case we discussed earlier today, the Claimant has made a point that that was a dangerous situation with the oversized tablet. This is exactly the same problem. An oversized tablet

1143

16:37:02 contains more drug than necessary.
So insofar as--what I'm reacting to here was, as I said, the trivialization of the safety problems associated--potentially associated with the Apotex products.
Q. You mean by FDA?
A. I mean by Apotex.
Q. By only classifying it--
A. I mean by the Claimant in this case.
PRESIDENT VEEDER: Counsel, please. Let the Witness finish.
BY MR. HAY:
Q. I'm sorry. Can you finish?
A. I mean trivialized by the Claimant in this case.
Q. It was classified a Class II by the FDA; correct?
A. Yes. And then your papers and the Report by Mr. Bradshaw and Johnson omitted any reference to transient or temporary health hazard. It simply talked about a remote risk of injury, thereby further trivializing the risk presented by any Class II

1144

16:37:53 product.
Q. The carbidopa-levodopa product--
A. Yes.
Q. --that has been discussed at length in this arbitration?
And you're aware, are you not, that the particular incident that you're referring to here was investigated by the FDA?
A. Yes.
Q. And the FDA said that Apotex's investigation and systems and reports with respect to it were all in compliance?
A. They fulfilled the minimum requirements of GMPs, yes.
Q. And Apotex--strike that.
FDA didn't do anything further with respect to that drug?
A. I believe that the activities--the actions included, if I recall correctly, [redacted]

1145

16:38:58 [redacted]
Q. And do you recall from the record that the FDA looked at that issue and didn't include it on the Etobicoke Warning Letter?
A. As Dr. Rosa said, Warning Letters never encompassed everything. They say this is not all inclusive. And my point--
Q. Can you answer my question?
A. Yes. It was not listed in the Warning Letter, as far as I recall.
Q. Okay. Thank you.
MR. HAY: We can go back to the...
PRESIDENT VEEDER: Let's go back.
SECRETARY TAYLOR: The feed is now on.

1146

16:40:05 NONCONFIDENTIAL PORTION
BY MR. HAY:
Q. Let me direct your attention to Paragraph 44 of your Report.
A. Yes.
Q. And in particular your last sentence says, "In my Opinion, these facts justify extending any regulatory action directed at Signet to include the Etobicoke facility."
Do you see that?
A. Yes.
Q. Are you opining that the Etobicoke facility should have received an Import Alert? Is that what that means?
A. No. What it means is that the fact that the system--quality control system was under the same management at both sites meant that the findings at one site, in light--because they were consistent with and expanded upon the findings at the other site and were consistent with them, justified regulatory actions at both sites.
Q. So it's not your Opinion that either the

1147

Etobicoke or Signet facilities should have received an Import Alert; correct?
A. The decision of what regulatory response the Agency should take in a given situation depends on a lot of variables. I was simply saying here that the Signet findings could be extrapolated back to the Etobicoke findings.
Q. I understand that that's your testimony, but my question was slightly different. My question was, are you rendering an Opinion as to whether or not the Signet or Etobicoke facility should have received an Import Alert?
A. No, I'm not rendering an Opinion on that at all.
Q. Okay. So you're not rendering an Opinion one way or another as to the enforcement action taken by FDA and whether it was justified; correct?
A. I'm rendering an Opinion that it was within the powers of the FDA to take action in this case. There was a sufficient factual record to justify it, and I'm saying in terms of the enforcement tools they had before them, they could select what tool they

1148

wanted to use.
So in that regard, if you want to use the word "justified," you can. I'm not sure I would use the word "justified." I think "authorized" is the word I would choose to use.
Q. So they had the power to make the decision, is what you're saying?
A. Yeah.
Q. Okay. But in terms of whether they should have or not, you're not rendering an Opinion; correct?
A. No.
Q. If you look at 45, the first sentence, it says, "Apotex and its Experts contend that a manufacturer situated outside the U.S. producing drugs for sale in the U.S. (such as Apotex) is subject to FDA regulatory enforcement actions and have the same--that have the same practical effect (specifically, banning drugs from the U.S. market for failure to comply with cGMPs) as one residing inside the U.S."
Do you see that?
A. I see that.

1149

Q. Yes. And is that a correct statement, that--is what Apotex and its Experts contend correct?
A. I believe that is what the contention is. That's what I thought I heard Mr. Bradshaw say when he said these options would have exactly the same effects.
Q. But my question is, is it correct that a manufacturer situated outside the U.S. producing drugs for sale in the U.S. (such as Apotex) is subject to FDA regulatory enforcement actions that have the same practical effect (specifically, banning drugs from the U.S. market for failure to comply with cGMPs) as one residing inside the U.S.? Is that a true statement?
A. No. As I say in the next sentence, in my Opinion, this assertion misleads the Tribunal about the applicable legal regimes.
Q. Okay. Let's break it down. A manufacturer situated outside the United States producing drugs for sale in the U.S. is subject to FDA regulatory enforcement action that could ban drugs from the U.S. marketplace for failure to comply with cGMPs; correct?
A. Can you read that, again, for me?

1150

Q. Sure.
A. What you just said, gotta read back.
Q. Okay.
PRESIDENT VEEDER: Do you have your Expert Report?
THE WITNESS: I have my Expert Report here. He just paraphrased something and then put it--a question.
MR. HAY: I'm not reading from his Report. I am--okay. I will state it again. Okay.
PRESIDENT VEEDER: Okay. Do.
BY MR. HAY:
Q. A manufacturer situated outside the U.S. producing drugs for sale in the U.S. is subject to FDA regulatory enforcement action that could ban drugs for U.S.--for the U.S. marketplace for failure to comply with cGMPs; correct?
A. Yes.
Q. A manufacturer situated inside the U.S. producing drugs for sale in the U.S. is subject to FDA regulatory enforcement action that could ban drugs from the U.S. marketplace for failure to comply with

cGMPs; correct?
A. Correct.
Q. At Paragraph 46 you discuss FDA's ability to gain access to domestic and foreign facilities.
Do you see that?
A. Yes.
Q. To conduct an inspection; correct?
A. Yeah.
Q. Now, if a domestic facility decides--denies FDA access for a cGMP inspection, the FDA has enforcement tools to prevent that domestic company from selling product in the United States; correct?
A. No, I don't believe that's correct. The--if I can, the failure to permit an inspection is a violation of the Act, but it does not render the products to be adulterated; and, therefore, the goods would not be subject to seizure. The injunction that would lie would be an injunction to mandate the manufacturer to permit access. It would not be a mandate to block shipment of the drug.
Q. So they wouldn't have a tool to go in and get an injunction based on the fact that they have been

denied access? Is that what your testimony is?
A. I don't believe they would. I've never seen that brought, but if you're looking at Section 301(e), I believe, of the Act which says that it's a crime to--it's a prohibited act to refuse an inspection, but it does not render the product to be adulterated.
So an injunction to stop shipment of the drug would not be related to the violation. An injunction would have to enforce the law or, you know, prohibit a further violation of law, which is refusal to have the inspection, not shipping drug.
Q. Okay. So they can only compel inspection? Is that what your testimony is?
A. That's what I'm saying, yes.
Q. So they can continue to sell the drugs?
A. Yes.
Q. Even though they denied the inspection?
A. Yes. Now, the FDASIA, was enacted in 2012, provides that a foreign inspection that does not--a foreign manufacturer that does not permit an inspection does result in the adulteration of that drug. So that would have a different outcome under

the statute.
Q. And that's in 2012?
A. Yes.
Q. The FDA has--well, let's direct you to 49, where you start talking about seizures. Let me ask--let me try and shortcut this.
The FDA has the legal authority to seize the products of a manufacturing facility intended for sale in the U.S. if the facility is in violation of the cGMPs; correct?
A. Again, with the 2012 amendments, they actually have extra-territorial jurisdiction.
I'm sorry. Was your question about U.S.-based facility?
Q. U.S. company. I'm sorry.
A. Okay. U.S.-based facility, yes.
Q. Okay. And the FDA has the legal authority to seize the product of a foreign manufacturer intended for sale in the U.S. either at the border or within the U.S. if that facility is in violation of cGMPs; correct?
A. If the manufacturing facility is in

violation, yes. In other words, if they're held at a distribution point, as long as the manufacturing site was--they could seize the products here, yes.
Q. Or if it was at the border, they could seize it.
A. Or at the border.
Q. In both cases, such seizure would be subject to the approval of a Federal judge; correct?
A. Yes.
Q. And so the FDA can also enjoin the sale of drugs in the United States by a domestic facility if that facility is in violation of the cGMPs; correct?
A. Enjoin the production of the facility, yes.
Q. And the FDA can enjoin the sale of drugs in the U.S. by a foreign facility if that facility is in violation of cGMPs; correct?
A. The injunction would lie against whoever had the drugs in the United States.
Q. They could--the FDA can enjoin the sale, the actual sale in the U.S.; correct?
A. Yes.
Q. In our particular case, for example, the FDA

1155

could have enjoined the sale by Apotex Corp. of any drugs in the U.S.; correct?
A. Yes.
Q. Okay. And they could have also enjoined the sale--strike that.
They could have also seized the drugs at the warehouse or at the border against Apotex Corp.; correct?
A. Yes.
Q. In your opening or direct testimony and in your Report, you talk about the FDA having certain discretion in making enforcement decisions; correct?
A. Yes.
Q. FDA's discretion is not absolute; correct?
A. I said that, yes.
Q. Okay. The FDA's discretion is subject to, among other things, law; correct?
A. That is such a broad statement that, you know--
Q. Let me rephrase it.
A. --God and country, too, yes.
Q. The FDA cannot exercise its discretion in a

1156

matter in violation of the law; correct?
A. What law?
Q. Any law.
A. I'm not being argumentative. "The law"--
Q. U.S. law.
A. --is a broad term.
I don't understand your question. I'm sorry.
Q. In exercising its discretion, the FDA is accountable for not violating--not doing so in a way that would violate U.S. law. Agree or disagree with that proposition?
A. I think I have to disagree with it as you're articulating it. And that is because the Supreme Court has held that FDA's exercise of enforcement discretion in bringing cases and so forth is not reviewable, generally, by U.S. courts.
Q. So it's absolute?
A. No. As I said before, there are cases that hold that--the selective prosecution, for example, punitive, you know, arbitrary prosecution of people for reasons--political reasons, for example, would be unacceptable.

1157

In the Heckler case, there was another decision about--another footnote dropped in which the Supreme Court noted an earlier case in the 1970s where the Nixon Administration had announced they were not going to enforce school busing anywhere in the country under Federal court orders. And the Supreme Court said, no, that's abdication of the statute. You cannot abandon the statute. You are subject to those kind of reviews.
But the day-to-day decision making about whether you bring a case against Company A versus Company B and whether you bring a seizure versus an injunction or whether you bring a criminal prosecution, those are--absent evidence of selective prosecution for improper motivation, are not reviewable by a Federal court.
So when you say it's subject to a rule of law, I'm not sure how one says it's accountable to somebody when there's no court to hold it accountable to.
Q. Well, is it the subject to the arbitrary and capricious standard, for example?

1158

A. No.
Q. It's not?
A. No.
Q. And so whatever the law is, the U.S. law is--and it can be established by the Parties in a particular case--whatever the law is, FDA is still subject to that in exercising its discretion?
A. There are limits on FDA's discretion. I have said that repeatedly. Selective prosecution for improper motives is clearly one. Abdication of a statutory duty is another. But it's not subject to the arbitrary and capricious standard of the Administrative Procedure Act.
Q. Let me direct you to Paragraph 76. In this paragraph, you're talking about one of the issues of the Sandoz shutdown, et cetera.
A. Yes.
Q. And where it talks--where you say "They cannot avoid the fact, however, that the company told FDA it would not ship any nonmedical necessary products to the U.S. while remedied its cGMP issues, thereby making an Import Alert unnecessary," do you

see that?
A. Yes.
Q. You have no cite for that. Is there some document you saw that you know that to be true?
A. I'm referring--the previous sentence I talk about the Second Report of Bradshaw at Paragraph 41 and the Counter-Memorial of the Government in Paragraph--Footnote 87 of 335. And I make the point that there seems to be a disagreement between the Parties in terms of what exactly Sandoz promised, and so forth.
My point was that it didn't make a difference as long as Sandoz had told the United States it would not ship any medically--nonmedically necessary products to the United States while it remedied problems.
Q. That's my question. What are you basing that they said that? Or don't you know they said that; you're assuming they said that?
A. I believe both Parties have said that, but if not, I'm relying on one of the two citations there. I have no independent knowledge of what happened there.

So those are the two sources of material, and whatever exhibits are attached that are recited in those two paragraphs.
MR. HAY: Can we take a short break so I can look through this and see if I can finish up quickly?
PRESIDENT VEEDER: You have 15 minutes left.
MR. HAY: Right.
PRESIDENT VEEDER: How long of a break?
MR. HAY: Five minutes.
PRESIDENT VEEDER: Five minutes. Yes. Let's take five minutes. Please don't discuss the case away from the Tribunal.
THE WITNESS: Thank you.
PRESIDENT VEEDER: Let's resume. Mr. Hay, how we doing time wise?
MR. HAY: I will be done very shortly.
PRESIDENT VEEDER: How short is done "shortly"?
MR. HAY: Hopefully a question.
PRESIDENT VEEDER: One question?
MR. HAY: Yes.
PRESIDENT VEEDER: Okay. Let's see how it goes. Thank you.

BY MR. HAY:
Q. Mr. Vodra, as part of your direct, you testified that you have advised clients that--in some instances where they've had cGMP issues, to stop shipping goods?
A. Yes.
Q. Have there been instances where you've advised clients to continue shipping goods while they work out and correct the cGMP issues?
A. Yes.
MR. HAY: Thank you. I have no further questions.
PRESIDENT VEEDER: Thank you. Are there any questions by way of reexamination from the Respondent?
MR. BIGGE: Yes. Just a few.

REDIRECT EXAMINATION

BY MR. BIGGE:
Q. Mr. Vodra, you were asked about whether FDA could obtain an injunction against Apotex Corp. to stop selling Apotex Inc. products in the United States. Had FDA done that, is there anything that

would have stopped Apotex Inc. from shipping its products to a different distributor and selling them in the United States?
A. No.
MR. HAY: Mr. President, that was a more than slightly leading question. If we could--
MR. BIGGE: I can rephrase, but the cat's a bit out of the bag.
PRESIDENT VEEDER: Try and rephrase.
BY MR. BIGGE:
Q. Had they obtained the injunction against Apotex Corp., would that have--sorry; it is hard to ask this in a nonleading way.
What would the effects have been on Apotex Inc. as the manufacturer?
A. The injunction would apply only to the Parties to the injunction, and unless Apotex Inc. were to subject itself to the jurisdiction of the Court, it would have no effect on Apotex Inc.
Q. You were also asked a number of questions about review of this decision. Now, if--I believe in your Report you talk about a detention hearing; is

that correct?
A. Yes.
Q. Had Apotex brought--had Apotex invoked its right to a detention hearing, can you walk the Tribunal through that process, including whatever appeals could have occurred?
A. Okay. Well, as I said, the Notice of the Detention, which is Notice Number 2 in the process, tells the owner and the consignee--owner in this case being the shipper--that the goods have been detained and that they are under review, and that the owner--and that the detention--basis of the detention is violation of--or noncompliance with GMP requirements, in this case.
Basically, the notice gives what the basis for the detention is and provides an opportunity for the Party to appear in person, by telephone, whatever, and present facts and information that would resolve whether the goods were admissible in the United States or not.
And the outcome of that, if the decision is to refuse admission to the United States, that that

becomes the final agency action. Anything before that point is not an agency action. That's Notice Number 3.
Then, at that point, there are various informal and formal remedies that would be available. You could appeal up the chain of command within the Office of Regulatory Affairs, because this a decision made at the district office, and that goes up to the Commissioner's office to the Associate Commissioner of Regulatory Affairs and all of the Commissioner's top-level staff, it goes outside the scope of CDER. So that would be one option.
The second route would be to use the formal dispute resolution procedure for GMP issues if the company felt that the GMPs were, in fact, complied with. And you saw presented--I don't know what the exhibit number was, but there's a mechanism that FDA has created for dispute resolution on scientific and technical issues in the GMP arena.
There would be a right--I say "a right." They could also, because it's a final agency action, seek judicial review under the Administrative

Procedure Act at that time. There is some question about the jurisdiction of federal courts with this, but I don't want to get into too much detail there. But the point is those would be at least three remedies.
Then, as I mentioned in my Report, there is the option of citizen's petition to the Commissioner or a petition to the Commissioner to reconsider the decision. Both of those are formal mechanisms that go directly to the Commissioner's office. The Commissioner could delegate that responsibility down to get the matter resolved. Those are, in my view, cumbersome, but they are remedies that are available.
Q. So had--strike that.
In discussing the standard of review, you said that--that discretionary decisions might be reviewable for selective prosecution for political reasons. Is there--does that have any applicability in this case?
A. Well, I don't know facts that have been alleged. Nothing I saw in the claims or the counterclaims even pose that possibility. I could

hypothecate, but I don't think it would be helpful.
Q. Just to clarify the record, you said that Apotex Corp. was the owner of goods in the Indianapolis warehouse. What was the basis, if any, of that Opinion?
A. I won't say it's a sophisticated legal analysis. In reading the documents, there was a great deal of discussion about when title transferred and who was owner of the goods and where the Transfer occurred and so forth. But I assumed that the goods, by the time they reached Indianapolis, were the property of Apotex Corp. They were listed as the consignee, which is normally who the goods are delivered to. I didn't get into--you know, I have no bills, no contractual, nothing that would--so if I'm wrong on that, I plead ignorance.
Q. Finally, you were asked repeatedly by Mr. Hay if FDA should have put Apotex on the Import Alert. Do you have--do you have any basis to arrive at an opinion on that question?
A. No. I mean, I've looked at an incredible, staggering number of documents in this matter, and the

decision-making process appeared to be reasonable and objective, and I have no reason to second-guess it. I wasn't there. I didn't know what other options that they might have considered. I didn't know what other pressures they were under in terms of resources and priorities and so forth. So I can't give an opinion that I would have thought they could have--they should have done something differently.

Q. What sort of factors go into the decision of whether to put a company on an Import Alert?

MR. HAY: Mr. President, this wasn't--my question was did he render an opinion on it, and his answer was no. So I'm a little surprised that we're now getting into this issue.

MR. BIGGE: I withdraw the question.

One more second. No further questions. Thank you.

PRESIDENT VEEDER: Thank you. The Tribunal has some questions.

QUESTIONS FROM THE TRIBUNAL

ARBITRATOR ROWLEY: Mr. Vodra, do you by any chance have the Bradshaw and Johnson Reports with you?

THE WITNESS: I'm sure they can be provided to me. My copies are heavily annotated and they told me not to bring them up. You want both Reports, First and Second?

ARBITRATOR ROWLEY: No. The first one.

THE WITNESS: The first one.

ARBITRATOR ROWLEY: And I'm going to ask you a question about something you said in Paragraph 14. So why don't you read Paragraph 14 before I ask you the question.

THE WITNESS: Paragraph 14.

ARBITRATOR ROWLEY: Bradshaw.

THE WITNESS: Okay. Thank you.

ARBITRATOR ROWLEY: First Report. Paragraph 14. Let me know what you've found it and read it.

THE WITNESS: I have, and it says it's relating to the relationship between--

ARBITRATOR ROWLEY: Sorry, it's the Second Report. I do apologize. I can see that everybody is so annoyed I think I probably don't want to ask the question.

THE WITNESS: Yes.

ARBITRATOR ROWLEY: When you were being cross-examined, you may remember there was a flurry of questions and interruptions when you were offering the suggestion that Claimant had trivialized--trivialized the risks associated with the Class II product--and its Class II product. And after the Chairman or President intervened, you continued with your answer and I'm going to read it to you because I have the transcript in front of me at 1130.

And you said, then, "Yes, and then your papers"--and you're referring to, I think, Claimants' papers--"and the Report by Mr. Bradshaw and Johnson omitted any reference to transient or temporary health hazard. It simply talked about a remote risk of injury, therefore, further trivializing the risk presented by any Class II product."

And when you said that, I had recalled the paragraph that I've drawn your attention to in the Bradshaw Report where they set out the full classification of Class II, which refers to temporary or medically reversible adverse health consequences.

And I wanted to draw your attention to the paragraph to see whether you would like to clarify your view about trivialization.

THE WITNESS: Yes. Thank you very much. I appreciate this opportunity. I stand corrected. It is quoted correctly here.

I was referring to Paragraph 22(b), where they switched to a discussion about "remote possibility," and that's where I felt they had moved off in a different direction.

PRESIDENT VEEDER: Just one question. Could you turn to Paragraph 74--I'm going to stop there because I'm going check--yes, it has to be your First and Second Report.

THE WITNESS: Yes.

PRESIDENT VEEDER: Your First Report.

THE WITNESS: Consolidated.

PRESIDENT VEEDER: I know. That's why I said it.

It's at Paragraph 74, and it's at Page 36. And you see below that you say, in Paragraph 75, "In my opinion, the August 17"--this is 2009--"telephone

1171

call appears to have been a turning point for FDA." And then you continue on Page 37, "Moreover, the company told FDA it intended to continue to distribute products into the U.S. market relying on its current quality system, the system that the company and FDA agreed was deficient and needed remediation. In my experience, FDA would have interpreted Apotex's response as lacking a real commitment to drug quality. A senior FDA official who participated in the August 17 teleconference put it succinctly six months later when he said Apotex did not take FDA too seriously." And you footnote the actual record of that press release--or statement to the press in Footnote 86.

But in Footnote 85, do you see at the bottom of the Page 37, you refer to the minutes of the telephone conference with Apotex on the 3rd of September, 2009.

And I just ask you first, did you intend that or would it be--(overlapping.)

THE WITNESS: No, that should be--

PRESIDENT VEEDER: I think you've answered my

1172

question.

Shall we look at minutes of the 17th of August of 2009, which is at R-43, CB--that is, the Core Bundle--Tab 25.

Can you be given that?

THE WITNESS: Yes. That was the first document I was given.

PRESIDENT VEEDER: Good. So that is the proper reference that we should look at rather than the minute--

THE WITNESS: Yes.

PRESIDENT VEEDER: --of September the 3rd.

THE WITNESS: Yes. The portion I was referring to was at the bottom of the first page, and The response at the top of the second page.

PRESIDENT VEEDER: What I want to ask you is, looking at this minute, or this draft minute, is there anything there which would indicate to you that Apotex were not taking the FDA too seriously. If so, what passage?

THE WITNESS: I would start with the statement JD at the top of page 2. "Apotex does

1173

intend to continue distributing. We believe we can deliver safe and efficacious product. With immediate effect, we've engaged an outside consulting group to help us address our deficiencies."

And then FDA comes back and is concerned about the distribution--and this is under CR. "Concerned about the decision to continue distributing in the U.S. market considering Apotex acknowledges significant deficiencies."

LL, who is Lance Lovelock, who is the Vice President for Quality, for the second time in the conversation acknowledged that there were significant deficiencies. But also indicated the potential for direct impact on quality was mitigated--on product quality was mitigated to a large degree by a variety of checks and balances that prevent products from entering the market when those types of deviations occur.

Now, he's saying this after informing the FDA they're going to recall 640 batches involving 400--42 different molecules that the system had not prevented from entering the market.

1174

And then it says, We've also done a good job in reporting issues to the deviation system. We don't--while this doesn't remove the need to improve the systems, it has been effective in ensuring issues are considered as part of any disposition decision.

And, in fact, as Dr. Rosa testified earlier today, they had made disposition decisions to release batches that did not conform to specifications and did not pass the appropriate tests. And so my reading of this--and these are minutes prepared by Apotex, and I thought it was significant that Apotex did not submit this document with their exhibits in support of their claim. Because this, to me, is a statement from the company that We think we're good enough and we're going to keep on going business as usual. We'll fix things as we get around to it, when the FDA was clearly quite concerned by the fact they asked for this phone call the first business day after the close of the inspection at Signet. There was just a complete disconnect between the two.

This is something I've seen before. It is not unusual. Companies frequently do not hear FDA

clearly until FDA basically hits them alongside the head with a 2 by 4.

PRESIDENT VEEDER: Thank you.

That's all the questions from the Tribunal. But are there any questions from the Parties? We ask the Respondent first?

MR. BIGGE: No.

PRESIDENT VEEDER: For the Claimant?

MR. HAY: Yes.

PRESIDENT VEEDER: Please proceed.

RECROSS EXAMINATION

BY MR. HAY:

Q. If you like at that same exhibit, R-043--and you were looking at the last page. If you can--

A. The last page.

Q. Yes, the last page of that exhibit, which is the meeting minutes that you were just discussing, you pointed out. At that point in time, Apotex told FDA that for some products they were going to stop shipping until the observations were resolved; correct?

A. Yes. For certain products.

Q. For certain products?

A. Yeah.

MR. HAY: No further questions.

PRESIDENT VEEDER: Any questions from the Respondent arising from that question?

MR. BIGGE: No.

PRESIDENT VEEDER: Thank you very much. We've come to the end of your testimony. You can leave everything there. Thank you.

(Witness steps down.)

MR. SHARPE: Mr. President, this concludes the presentation of the United States's Witnesses and Expert. We have another 35 minutes, so with the Tribunal's permission, we'll proceed with our jurisdictional arguments, and we'll call on Ms. Thornton.

PRESIDENT VEEDER: Please do. Thank you.

PRESENTATION-IN-CHIEF BY COUNSEL FOR RESPONDENT

PRESIDENT VEEDER: Please proceed.

MS. THORNTON: Good afternoon, President Veeder, Mr. Rowley, Mr. Crook. My name is Nicole Thornton, and it's an honor to appear before you today

representing the United States. The focus of my presentation over--well, until the end of the day--I'm not sure I'll be able to get through it all. It's about a 45-minute presentation, but I'd leave it to you whether we go slightly over--will be the preclusive effect of the Apotex I and II Award on Apotex Inc.'s jurisdictional claim in this arbitration.

Ms. Grosh mentioned yesterday that the Apotex I and II award held that Apotex Inc. was not a qualifying investor under the NAFTA because its generic drug applications, or ANDAs, are not investments in the United States under Article 1139. Consequently, this key jurisdictional issue between Apotex Inc. and the United States involving the same NAFTA Treaty provisions has been litigated and determined and is res judicata.

I will begin my presentation today by summarizing our position as stated in our Rejoinder. Then I will discuss Apotex's three main objections. In particular, I will walk through the record in the previous arbitration and demonstrate how the

jurisdictional issue before the Tribunal concerning Apotex Inc.'s alleged status as an investor by virtue of its ANDAs was actually arbitrated and determined in the previous Award.

As the United States explained in its Rejoinder, the Apotex I and II Tribunal decided the identical jurisdictional issue presented by Apotex Inc. in this arbitration; namely, whether Apotex's ANDAs constitute investments for purposes of Article 1139 such that Apotex Inc. qualifies as an investor for purposes of Article 1116.

The Apotex I and II Tribunal determined that ANDAs, whether tentatively or finally approved, are not covered investments under Article 1139, and so Apotex Inc. is not a qualifying investor for purposes of Article 1116. Accordingly, the previous Tribunal dismissed all claims by Apotex Inc. for lack of jurisdiction. The Apotex I and II Award is res judicata and precludes relitigation of the identical jurisdictional issue in this arbitration, which involves the same provisions of the NAFTA and the same Parties.

1179

17:27:40 Res judicata is a well-established general principle of international law. As the Waste Management II Tribunal observed in its Decision on Mexico's preliminary objection concerning the previous proceedings, "there is no doubt that res judicata is a principle of international law and even a general principle of law within the meaning of Article 38(1)(c) of the Statute of the International Court of Justice."

Res judicata, therefore, applies to these proceedings pursuant to the NAFTA Article 1131(1), which provides that "A Tribunal established under this Section shall decide the issues in dispute in accordance with this Agreement and applicable rules of international law."

Res judicata serves at least two significant functions: Ensuring the finality of litigation and protecting against vexatious litigation in the form of repeated or multiple claims. As the International Court of Justice, or ICJ, explained in the Genocide case: Two purposes, one general, the other specific, underlie the principle of res judicata. First, the

1180

17:28:53 stability of legal relations requires that litigation come to an end. Secondly, it is in the interest of each Party that an issue which has already been adjudicated in favor of that Party be not argued again. Depriving a litigant of the benefit of a judgment it has already obtained must, in general, be seen as a breach of the principles governing the legal settlement of disputes.

In 2006, the ILA Committee on International Commercial Arbitration presented its Final Report and "Recommendations on Res Judicata and Arbitration." This Report and Recommendations were the culmination of a four-year study by the Committee incorporating observations by scholars and practitioners. The recommendations as adopted by the ILA recognized that an Arbitral Award is conclusive and preclusive where it has become final and binding; has disposed of a claim for relief sought or reargued in further arbitral proceedings; is based on upon the same cause of action in subsequent proceedings or forms the basis for subsequent proceedings; and has been rendered between the same Parties.

1181

17:30:03 Arbitral Awards also have conclusive and preclusive effects in subsequent arbitral proceedings as to "determinations and relief contained in its dispositive part as well as in all reasoning necessary thereto; and issues of fact or law which have actually been arbitrated and determined by it, provided any such determination was essential or fundamental to the dispositive part of the arbitral award."

Recommendation for 4.1 endorses the more extensive notion followed in public international law under which res judicata not only is to be read from the dispositive part of Award, but also from its underlying reasoning.

PRESIDENT VEEDER: 4.2. Not 4.1.

MS. THORNTON: I apologize. Yes. 4.2.

Recommendation of 4.2 endorses common law concepts of issue estoppel which, for reasons of procedural efficiency and finality, seem to be acceptable on a worldwide basis notwithstanding the fact they are yet unknown in civil law jurisdictions.

Of course, both United States, with New York as the seat in both Apotex arbitrations, and Canada

1182

17:31:18 recognize and apply issue estoppel. The ILA Final Report also confirmed that issue estoppel applies not only to the same claim, but to also different claims in further arbitral proceedings.

Apotex Inc.'s jurisdictional claim falls squarely within the ILA's Recommendations on Res Judicata and Arbitration. First, the Parties are the same. In both cases, Apotex Inc. is a Claimant and the United States is the Respondent. Second, a key jurisdictional issue in both arbitrations is the same, notwithstanding different claims raised on the Merits. In both cases, Apotex Inc. contends that it qualifies as an investor whose ANDAs constitute investments in the United States for purposes of NAFTA Articles 1116 and 1139.

Third, the jurisdictional issue was fully arbitrated and determined in the Apotex I and II Award. The Parties argued the issue over two rounds of briefing and an oral hearing. The Tribunal issued a unanimous, lengthy, and reasoned Award determining the issue in its operative part as well as the associated reasoning, and that determination was

essential to its dispositif.

Fourth, the Apotex I and II Tribunal decided the issue in a final and binding Award. It is well established that jurisdictional Awards, such as the Apotex I and II Award, have preclusive effect between the Parties with respect to the issues decided. The Waste Management I and II Tribunal observed that, "at whatever stage of the case it is it decided, a decision on a particular point constitutes a res judicata as between the Parties to that decision if it is a necessary part of the eventual determination and is dealt with as such by the Tribunal."

Similarly, the ILA Final Report confirmed that its recommendations are intended to apply to partial final Awards, final Awards, and Awards on jurisdiction. Thus, the Apotex I and II Award is res judicata as to a key jurisdictional issue in this case, and Apotex should be precluded from relitigating it.

Not surprisingly, Apotex contends that the Apotex I and II Award is not res judicata, raising

three main objections. I will focus the next part of my presentation on these points of disagreement between the Parties; namely, whether Article 1136(1) of the NAFTA contemplates that Awards may have preclusive or res judicata effect beyond the confines of the particular case; whether the scope of res judicata includes the concept of issue estoppel; and the--whether the jurisdictional issue before us in this case was actually litigated and determined in the Apotex I and II Award and was essential to its judgment.

On the first point, NAFTA Article 1136(1) provides that an Award made by a Tribunal shall have no binding force except between the disputing Parties and in respect of the particular case. According to Apotex, Article 1136(1) means that the Apotex I and II Award can have no preclusive effect with respect to the present arbitration. But Apotex acknowledge, as it must, that the language of the NAFTA Article 1136(1) and the language of Article 59 of the ICJ statute are essentially identical.

We've put the language of Article 59 also on

the slide.

So according to Apotex's logic, Article 59 would preclude application of res judicata in the ICJ given that the decision of the Court has no binding force except between the Parties and in respect to that particular case. But obviously that's not true. Res judicata was cited as an example of the general principles of law by Lord Phillimore of the Advisory Committee of Jurists to describe the possible content of Article 38(3) of the Statute of the Permanent Court of International Justice, the predecessor to the ICJ statute.

And, of course, Apotex acknowledges correctly that the ICJ recognizes the binding force and res judicata effect of its decisions. Indeed, the ICJ has not limited the binding force or res judicata effect of its prior determinations strictly and inflexibly to the particular case. For example, in the Haya de al Torre case, which followed the Asylum case, the Court had to consider an intervention by the Government of Cuba. The Court noted the intervention was devoted almost entirely to a discussion of

questions which the previous judgment in the Asylum case decided with the authority of res judicata.

The Court allowed Cuba's intervention only with respect to a new aspect of interpretation of the Havana Convention which the Court had not considered in the prior judgment. The Court's reasoning shows that its prior determinations may, in some instances, have preclusive effects beyond the particular case.

It is clear that the ICJ does not regard Article 59 as prohibiting the application of res judicata. Likewise, there is no basis for Apotex to assert that NAFTA Article 1136(1), which is worded almost identically, would bar the res judicata effect of the Apotex I and II Award here. Indeed, the Waste Management II Tribunal indicated as much when it acknowledged that--when it acknowledged the potential application of res judicata in the present proceedings to the extent that any issue already decided between the Parties may prove to be relevant at a later stage.

And I just want to pause a moment here with respect to President Veeder's question on Monday concerning Apotex's interpretation of Article 1136(1).

17:37:26 Counsel was asked why, given its interpretation, Apotex Inc. could not just bring another arbitration against the United States concerning the very same issues. Counsel for Apotex acknowledged that the "particular case" meant the "dispute." This is Day 1, Page 163 of the transcript.

In our view, the scope of the dispute concerns the issues that were litigated and determined as part of that dispute. An Arbitral Award decides that dispute between the Parties for all time as a whole and with respect to its constituent parts. I plan to flesh this out in the next section of my presentation.

I also want to address Apotex's argument concerning the high fructose corn syrup cases. Apotex asserts that "under at least the U.S. national law variation of issue estoppel," Mexico would have been precluded from arguing that the Measure in those cases did not breach the NAFTA after the first Tribunal dealt with the issue. And that's Day 1, Page 160 of the transcript.

Of course, those cases all involved different

17:38:40 Claimants who are not privies. In fact, they were all competitors. The United States is not arguing that this Tribunal should abandon the mutuality requirement and the ILA Final Report on Res Judicata and Arbitration was quite clear: That there was insufficient worldwide support for the extension of issue estoppel to third Parties. What the United States advocates is simply the application of issue estoppel as it is recognized in internationally, which requires the same Parties.

With respect to the second point of disagreement between the Parties, the principle of res judicata is broad and includes the concept of issue estoppel. Apotex denies that the ILA Recommendations on Res Judicata and Arbitration reflect existing law or that the--or that issue estoppel forms part of public international law today.

Apotex is wrong. The broad scope of res judicata has been articulated by multiple International Tribunals over the last 100 years, including in the early Orinoco Steamship case. That decision famously described res judicata in the

17:39:55 following terms: "The general principle announced in numerous cases is that a right, question, or fact distinctly put in issue and directly determined by a court of competent jurisdiction as a ground of recovery, cannot be disputed."

Apotex denies that the Orinoco case illustrates the scope of res judicata under international law because that case quoted from a U.S. Supreme Court case, Southern Pacific Railway Company. Apotex ignores the fact, however, that the decision on jurisdiction in the Amco v. Indonesia resubmitted case endorsed Orinoco's formulation stating that "The general principle announced in numerous cases is that a right, question, or fact distinctly put in issue and distinctly determined by a court of competent jurisdiction as a ground of recovery, cannot be disputed."

Of course, the three eminent jurists of that Tribunal--Per Magid, Rosalyn Higgins, and Marc Lalonde--were applying international as well as Indonesian law. Counsel for Apotex also suggested that there had been no explicit decision from a

17:41:08 prominent Tribunal endorsing the notion of issue estoppel. As the Grynberg/RSM v. Grenada Award found, also citing the Southern Pacific Railway case, the doctrine of issue estoppel is now well established as a general principle of law. The relevant language of that Award is on the slide.

And I just want to note here that although the term "collateral estoppel" is used in the language of that Award, it appears clear the Tribunal was not applying the American concept of the term because it was discussing issue preclusion generally throughout the Award and also it had to analyze whether the Claimants, the Shareholders of RSM, would be bound as privies, which it would not have done if it were applying the American notion of collateral estoppel.

In order to determine the precise question, fact, or issue determined in a prior Award, it is often necessary to refer to the Award's reasoning. Of course, the reasons for a Judgment or Award must generally be provided in that Judgment or Award. Article 32 of the UNCITRAL Rules, which governed the Apotex I and II arbitration, provides that an Award

1191

17:42:29 shall be final and binding on the Parties and that the Tribunal shall "state the reasons upon which the Award is based, unless the Parties have agreed that no reasons are to be given."

Article 52 of the ICSID (Additional Facility) Arbitration Rules, which govern this arbitration, similarly provides that an Award shall be final and binding on the Parties and shall contain the decision of the Tribunal on every question submitted to it together with the reasons upon which the decision is based. The ICJ statute and Commercial Arbitration Rules, such as the ICC and LCIA rules each have similar provisions.

As President Veeder has also observed, an Award's reasons are important because the purpose of an Award is to decide the Parties' dispute for all time, both as to the whole and to its constituent parts.

A long line of international jurisprudence recognizes that reasons provided in a decision are also res judicata to the extent that those reasons are relevant to the actual decision on the question at

1192

17:43:35 issue.

As early as 1902, the ad hoc Tribunal in the Pious Fund of the Californias case held that all parts of a Judgment or a Decree concerning the points debated in the dispute enlightened and mutually supplement each other, and that they all serve to render precise the meaning and the bearing of the dispositif and to determine the points of upon which there is res judicata and which, therefore, cannot be put in question.

As I already mentioned, the ILA recommendations endorse the more extensive notion of res judicata as applying not only to the dispositive part of an Award, but also its underlying reasoning. And the ILA Committee explains that more restrictive notions of the scope of res judicata limiting conclusive and preclusive effects to the dispositive parts of Awards have not been followed in the Recommendations because the Committee considered the latter notion to be overly formalistic and literal.

The logical conclusion to be drawn from the fact that final and binding arbitral Awards must

1193

17:44:46 contain the reasons and that res judicata extends to those reasons is that res judicata includes the concept of issue estoppel.

Before leaving this point, I want to address briefly Apotex's argument that the object and the cause, as well as one of the Parties are the different in the current arbitration. According to Apotex, because the traditional Triple Identity Test for res judicata is not met, the Apotex I and II Award has no preclusive effect. Apotex's facile argument confuses issue preclusion and claim preclusion.

It is certainly true that the traditional Triple Identity Test for claim preclusion requires the identity of Parties, identity of cause, and identity of object or subject matter in the proceedings. A Final Award finding a lack of jurisdiction generally does not have preclusive effects concerning Merits because such Awards did not reach the Merits. Final jurisdictional Awards are preclusive, however, with respect to the jurisdictional issues that were decided in the earlier Award. Thus, the fact that the object and cause of Apotex's Merits claims in this

1194

17:45:59 arbitration differ from the object and cause of Apotex's Merits claims in the previous arbitration is beside the point.

The fact that Apotex has added Apotex Holdings as a Party to the current arbitration also has no bearing on the matter. To be clear, the United States is not arguing that the Apotex I and II Award has any preclusive effect with respect to Apotex Holdings' claim to be an investor by virtue of its investment in Apotex Corp, a jurisdictional issue obviously not arbitrated or determined in the previous proceeding.

To the extent that Apotex Holdings purports to be an investor based on its ownership and control of Apotex Inc. and its investments in the ANDAs, its claim is merely derivative, dependent upon and identical to Apotex Inc.'s status as an alleged investor. The Grynberg/RSM v. Grenada Tribunal found that had three Shareholders of RSM--three Shareholders of RSM and RSM were privies. That Award recognized that the Shareholders were seeking damages suffered through RSM for alleged violation violations of RSM's

1195

17:47:15 legal rights. And that's Paragraph 7.1.6 that Award.
Moreover, the Tribunal noted that as Shareholders claiming standing based on indirect interest in corporate assets, they must be subject to defenses that would be available against the corporation, including collateral estoppel. That's paragraph 7.1.7.
The same is true here with respect to Apotex Holdings and Apotex Inc. It is not unfair to hold Apotex Holdings to the results of the prior Award with respect to the ANDAs.
Finally on this point, assuming the Triple Identity Test were relevant, the Parties, object, and cause of Apotex's jurisdictional claim to be an investor under NAFTA Article 1116 with an alleged investment under Article 1139 in both arbitrations is precisely the same. The relevant test for issue estoppel, however, is whether the jurisdictional question or issue was actually litigated and determined in the prior Award and whether that determination was essential to the judgment.
This brings me to the next section of my

1196

17:48:23 presentation and the third point of disagreement between the Parties.
On the third point of disagreement, the jurisdictional question of whether Apotex Inc. qualifies as a NAFTA investor with an investment in its ANDAs was actually litigated and determined in the prior Award. Apotex denies this and raises two alleged distinctions between the former and the present proceedings.
First, Apotex contends that the Apotex I and II Award addressed whether its drug applications for two products could be considered property under Article 1139 in the context of court and FDA decisions concerning those applications. Apotex says the current arbitration addresses ANDAs for scores of other products that can be considered as investments under Article 1139(g) and (h) in the context of an Import Alert that prevented their marketing. The number of Apotex's ANDAs is not material. If one ANDA cannot constitute an investment owing to its inherent nature, neither can scores of ANDAs.
Moreover, the different contexts--namely, of

1197

17:49:39 court and FDA decisions in the previous arbitration and of the Import Alert in the current arbitration--relate solely to Apotex's claims to the Merits. Again, Apotex confuses issue preclusion with claim preclusion and fails to rebut the United States's argument. That argument being that the prior Award's determination with respect to the jurisdictional issue of whether ANDAs may constitute an investment under Article 1139 applies to the identical jurisdictional issue posed here.
Second, Apotex asserts that the issue before the previous Tribunal was whether mere applications for an authorization to market drugs could constitute an investment under the NAFTA, even though the applications had not yet been finally approved.
Apotex contends that finally approval ANDAs, which it refers to as Marketing Authorizations, are materially different from tentatively approved ANDAs for purposes of Article 1139(g).
I would note again that FDA regulations establishing the process whereby manufacturers submit their Abbreviated New Drug Applications, or ANDAs, do

1198

17:50:53 not refer to ANDAs as Marketing Authorizations. An ANDA may be in various stages of preparation and, once filed, in various stages of review or approval with FDA. But an ANDA remains at all times a drug application subject to FDA oversight and revocation.
In this connection, I'll just note that Apotex has stated that at the time it brought the Apotex I and II claims, Apotex Inc. held over 150 finally approved ANDAs. And that's Day 1, Page 74 of the transcript.
So Apotex Inc. today is situated no differently than it was when it brought the Apotex I and II claims. If Apotex believed that there was a difference between finally approved ANDAs and tentatively approved ANDAs for purposes of its NAFTA Chapter 11 claim, it would have claimed to be an investor in the United States based on both finally approved and tentatively approved ANDAs. But it did not.
Apotex's newfound distinction between tentatively and finally approved ANDAs is even belied by its own position in the present proceeding. In its

17:52:07 Reply, Apotex argued that "Each ANDA reflects proprietary information concerning the drug's formulation, development, testing, and the manufacturing processes for the commercialization of the drug in the U.S. All of that information, even if developed in Canada, is committed to the United States upon the filing of the ANDA." Thus, according to Apotex, the investment is made upon the filing of the ANDA, not after it is approved.

In any event, any alleged distinctions between tentatively and finally approved ANDAs were fully arbitrated over two rounds of briefing and an oral hearing. The Apotex I and II Tribunal explored and considered the Parties' arguments on this distinction in its Award.

I only have five minutes. But I will begin to walk the Tribunal through the record in the previous arbitration on this point.

PRESIDENT VEEDER: I mean, if it's a convenient time to break, don't kill yourself. Do you want to break now?

MS. THORNTON: I'll just keep going until you

17:53:18 tell me to stop.

PRESIDENT VEEDER: Well, we can go to 6:00, but if this a convenient time to break for you.

MS. THORNTON: Sure. Because going through the record in the previous case is a whole section.

PRESIDENT VEEDER: Let's stop you here.

MS. THORNTON: Thank you. All right.

PRESIDENT VEEDER: Because we can spend a few minutes, I think, just planning for tomorrow. Thank you very much.

MS. THORNTON: Sure.

PRESIDENT VEEDER: Just for tomorrow, because we would wish to finish at 5:00 p.m., we would prefer starting the hearing tomorrow at 8:00 a.m. to make sure we do a full day, 8:00 a.m. to 5:00 p.m. Does that cause any difficulties?

We ask the Respondents first because it's the time when they present their case.

MR. SHARPE: I think we can accommodate the Tribunal's wishes. Thank you.

PRESIDENT VEEDER: Thank you very much.

For the Claimants?

17:54:00 MR. LEGUM: No difficulty for us.

PRESIDENT VEEDER: At some stage tomorrow we're going to announce our decision as regards closing oral submissions, but we'll do that probably in the afternoon at some convenient break rather than try and do it at 8:00. But we must do it, so if we overlook it, please remind us.

Is there anything else by way of housekeeping we need to address tomorrow? We ask the Claimants first.

MR. LEGUM: Only a request for a double ration of coffee for tomorrow morning.

PRESIDENT VEEDER: We'll do that. This place does everything, as you know.

The Respondent, anything further?

MR. SHARPE: Nothing further from the Respondent, Mr. President. Thank you.

PRESIDENT VEEDER: Thank you very much. We'll see you at 8:00 a.m. tomorrow. Thank you.

(Whereupon, at 5:54 p.m., the hearing was adjourned until 8:00 a.m. the following day.)

CERTIFICATE OF REPORTER

I, Dawn K. Larson, MBA-RDR, do hereby certify that the foregoing proceedings were stenographically recorded by me and thereafter reduced to typewritten form by computer-assisted transcription under my direction and supervision; and that the foregoing transcript is a true and accurate record of the proceedings.

I further certify that I am neither counsel for, related to, nor employed by any of the parties to this action in this proceeding, nor financially or otherwise interested in the outcome of this litigation.

_____

DAWN K. LARSON